

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

**Amendment No. 1 to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

Compass Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)

82-4876496
(I.R.S. Employer
Identification Number)

245 First Street
3rd Floor
Cambridge, Massachusetts 02142
(617) 500-8099
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Thomas J. Schuetz
245 First Street
3rd Floor
Cambridge, Massachusetts 02142
(617) 500-8099
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Richard A. Hoffman
James Xu
Goodwin Procter LLP
100 Northern Avenue
Boston, Massachusetts 02210
(617) 570-1305

Ivan K. Blumenthal
Daniel A. Bagliebter
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
666 Third Avenue
New York, New York 10017
(212) 692-6712

As soon as practicable after effectiveness of this registration statement.
(Approximate date of commencement of proposed sale to the public)

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.
If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated filer Accelerated filer
Non-accelerated Filer Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Exchange Act.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)(3)
Common stock, par value \$0.0001 per share	\$62,100,000	\$6,776

- (1) Includes additional shares of common stock that the underwriters have the option to purchase.
(2) Calculated pursuant to Rule 457(o) under the Securities Act of 1933, as amended, based on an estimate of the proposed maximum aggregate offering price.
(3) \$5,455 of such amount was previously paid in connection with the original filing of this Registration Statement.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

[Table of Contents](#)

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED NOVEMBER 9, 2020

PRELIMINARY PROSPECTUS



9,000,000 Shares of Common Stock

We are offering 9,000,000 shares of common stock of Compass Therapeutics, Inc.

We expect the public offering price to be between \$5.00 and \$6.00 per share. No public market currently exists for our common stock. We have applied to list our common stock on The Nasdaq Capital Market under the symbol "CMPX". No assurance can be given that our application will be approved.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

We are an "emerging growth company" as defined under the federal securities laws and, as such, are eligible for reduced public company reporting requirements. See "Prospectus Summary—Emerging Growth Company".

Investing in our common stock involves a high degree of risk. Before making an investment decision, please read "[Risk Factors](#)" on page 12 of this prospectus.

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

	Per Share of Common Stock	Total
Public offering price	\$	\$
Underwriting discounts and commissions(1)	\$	\$
Proceeds to us (before expenses)	\$	\$

(1) See "Underwriting" for additional information regarding underwriting compensation.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase an additional 1,350,000 shares of common stock at the public offering price, less the underwriting discount. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$, and the total proceeds to us, before expenses, will be \$.

The underwriters are offering the common stock as set forth under "Underwriting." The underwriters expect to deliver their shares on or about , 2020.

Joint Book-Running Managers

Citigroup

Credit Suisse

Stifel

Co-Manager

Raymond James

Prospectus dated , 2020.

TABLE OF CONTENTS

	PAGE
ABOUT THIS PROSPECTUS	ii
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	iii
PROSPECTUS SUMMARY	1
THE OFFERING	9
SUMMARY FINANCIAL DATA	10
RISK FACTORS	12
USE OF PROCEEDS	67
DIVIDEND POLICY	68
CAPITALIZATION	69
DILUTION	70
DESCRIPTION OF THE MERGER, THE PRIVATE PLACEMENT AND RELATED TRANSACTIONS	72
DESCRIPTION OF OUR BUSINESS	74
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	115
DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS	134
EXECUTIVE COMPENSATION	142
CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS	149
MARKET INFORMATION FOR OUR COMMON STOCK	152
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	153
DESCRIPTION OF CAPITAL STOCK	156
SHARES ELIGIBLE FOR FUTURE SALE	160
UNDERWRITING	162
LEGAL MATTERS	168
EXPERTS	168
WHERE YOU CAN FIND MORE INFORMATION	169
FINANCIAL STATEMENTS	F-1
INFORMATION NOT REQUIRED IN THE PROSPECTUS	II-1

ABOUT THIS PROSPECTUS

This prospectus describes the specific details regarding this offering and the terms and conditions of the common stock being offered hereby and the risks of investing in our common stock. We have not authorized anyone to give you any information other than the information contained in this prospectus, the information incorporated by reference herein, or any applicable prospectus supplement or any free writing prospectus filed with the Securities and Exchange Commission, or the SEC. We take no responsibility for, and can provide no assurances as to the reliability of, any other information that others may give you. We have not have authorized anyone to provide you with additional information or information different from that contained in this prospectus filed with the SEC. You should read this prospectus, any information incorporated by reference herein and the additional information about us described in the section entitled “*Where You Can Find More Information*” before making your investment decision.

We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. You should assume that the information appearing in this prospectus, the applicable prospectus supplement and any related free writing prospectus is accurate only as of the respective dates of those documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

For Non-U.S. investors

We have not done anything that would permit this offering or possession or distribution of this prospectus, any prospectus supplement or free writing prospectus filed with the SEC, in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus, any prospectus supplement or free writing prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus, any prospectus supplement or free writing prospectus outside the United States.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled “Risk Factors”, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Description of our Business”, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements relate to, among others, our plans, objectives and expectations for our business, operations and financial performance and condition, and can be identified by terminology such as “may”, “should”, “expect”, “intend”, “plan”, “anticipate”, “believe”, “estimate”, “predict”, “potential”, “continue” and similar expressions that do not relate solely to historical matters. Forward-looking statements are based on management’s belief and assumptions and on information currently available to management. Although we believe that the expectations reflected in forward-looking statements are reasonable, such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by forward-looking statements.

Forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the timing, progress and results of preclinical studies and clinical trials for CTX-471, CTX-8371, CTX-8573 and any other product candidates we develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing or likelihood of regulatory filings for CTX-471, CTX-8371, CTX-8573 and any other product candidates we develop and our ability to obtain and maintain regulatory approvals for such product candidates for any indication;
- our expectations regarding the potential benefits, activity, effectiveness and safety of CTX-471, CTX-8371, CTX-8573 and any other product candidates we develop;
- our intentions and ability to successfully commercialize our product candidates;
- our expectations regarding the nature of the biological pathways we are targeting;
- our expectations for our NKp30 innate cell engager platform, including our ability to discover and advance product candidates using our NKp30 innate cell engager platform;
- our estimates regarding the use of proceeds from this offering, expenses, future revenues, capital requirements and our need for or ability to obtain additional financing, together with our current cash, cash equivalents and marketable securities, to fund our operations;
- our intended reliance on and the performance of third parties, including collaborators, contract research organizations and third-party manufacturers;
- our ability to protect and enforce our intellectual property protection and the scope and duration of such protection;
- developments and projections relating to our competitors and our industry, including competing therapies;
- the impact of current and future laws and regulations;
- the impact of the coronavirus disease 2019, or COVID-19, pandemic on our business, results of operations and future growth prospects; and
- other risks and uncertainties, including those listed under the caption “Risk Factors”.

[Table of Contents](#)

These statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled “Risk Factors” and elsewhere in this prospectus, in any applicable prospectus supplement and in any related free writing prospectus.

Any forward-looking statement in this prospectus, in any applicable prospectus supplement and in any related free writing prospectus reflects our current view with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our business, results of operations, industry and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus, any applicable prospectus supplement and any related free writing prospectus and the documents that we reference therein and have filed with the SEC as exhibits thereto completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This prospectus contains, and any applicable prospectus supplement and any related free writing prospectus may contain, estimates, projections and other information concerning our industry, our business and the markets for certain therapeutics. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources that we believe to be reliable. In some cases, we do not expressly refer to the sources from which such data are derived.

SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in the securities covered by this prospectus. For a more complete understanding of the Company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus, any related prospectus supplement and any related free writing prospectus, including the information set forth in the section titled “Risk Factors” in this prospectus, any related prospectus supplement and any related free writing prospectus in their entirety before making an investment decision.

All references to “Compass OpCo” refer to Compass Therapeutics LLC, a privately held Delaware limited liability company and our direct, wholly owned subsidiary. Unless otherwise stated or the context otherwise indicates, references to the “Company”, “we”, “our”, “us” or similar terms refer to Compass Therapeutics, Inc. (formerly named Olivia Ventures, Inc.) together with its wholly-owned subsidiary, Compass OpCo. Compass OpCo holds all material assets and conducts all business activities and operations of Compass Therapeutics, Inc.

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 a 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 and 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 followed by a dose expansion cohort. The dose escalation stage of the Phase 1 trial has been completed and the dose expansion stage has been initiated, with the first patient dosed in September 2020. We aim to complete the Part 2 cohort expansion portion of the trial by the second half of 2021 and to initiate a Phase 2/3 trial of CTX-471 by early 2022.

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/or with cetuximab, marketed as Erbitux® by Eli Lilly, in epidermal growth factor receptor, or EGFR, positive tumors. We aim to submit an IND application for CTX-471 in combination with trastuzumab by early 2021 and are targeting the first patient first visit in the first half of 2021. We expect to generate top-line data from the Phase 1b trial of CTX-471 in combination with trastuzumab in the first half of 2022.

In addition to CTX-471, we are also developing a portfolio of bispecific antibody product candidates, which are currently in preclinical development. These programs were generated 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 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 properties. Third, we have developed proprietary technology StitchMabs™ 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 or 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. However, 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 observed 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. IND-enabling studies with CTX-8371 were initiated in August of 2020. We are targeting our second IND submission for CTX-8371 in the third quarter of 2021 and our first patient first visit in the second half of 2021. We aim to deliver early safety and top-line data in 2022.

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 gd T-cells. We have observed 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% to 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 dropped 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. We aim to make our third IND submission for CTX-8573 in late 2021 or early 2022 and to enter clinic by early 2022.

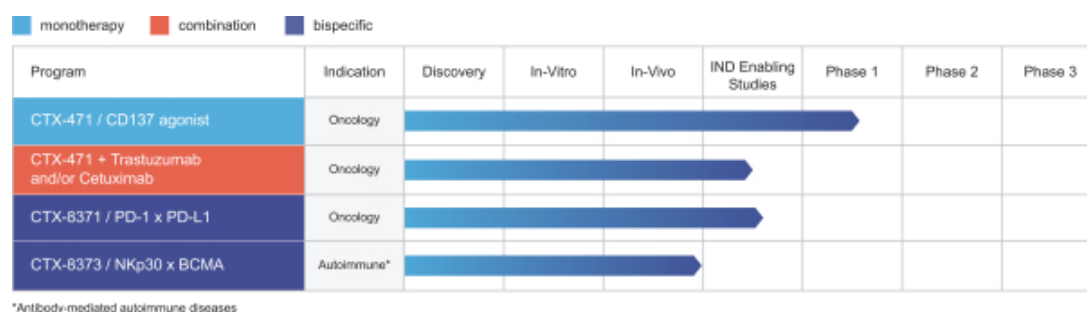
Our management team has a successful record of building and growing biotechnology companies. Our Chief Executive Officer and co-founder, Thomas J. Schuetz, M.D., Ph.D., has over 20 years of experience in oncology, biopharmaceutical drug development and life science venture investing. Prior to co-founding Compass Therapeutics LLC, Dr. Schuetz was a venture partner with OrbiMed Advisors LLC, or OrbiMed 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 President and Chief Operating Officer, Vered Bisker-Leib, Ph.D., M.B.A., has over 18 years of experience in strategy, business development, finance and operations of biotechnology and pharmaceutical companies. Prior to joining Compass OpCo, 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. 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 for prior offerings by our predecessor, Compass Therapeutics LLC, includes 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 preclinical programs: CTX-8371 and CTX-8573.



Our 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 at least 3 months of stable disease on

prior checkpoint therapies. We expect to report data from Part 2 of the Phase 1 trial, the dose expansion portion of the trial, in the first half of 2021. The dose escalation portion of the Phase 1 trial is complete. We aim to complete the Part 2 cohort expansion portion of the trial by the second half of 2021 and to initiate a Phase 2/3 trial of CTX-471 by early 2022. In addition, we aim to submit an IND application for CTX-471 in combination with trastuzumab by early 2021 and are targeting the first patient first visit in the first half of 2021. We expect to generate top-line data from the Phase 1b trial of CTX-471 in combination with trastuzumab in the first half of 2022.

- **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. IND-enabling studies with CTX-8371 were initiated in August 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 deplete 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 clinical development expertise to maximize the value of our pipeline.

Risks Related to Our Business

- Our ability to implement our current business strategy is subject to numerous risks, as more fully described in the section titled “Risk Factors”. These risks include, among others, the following:
- 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 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.

- 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.
- 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.
- 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.
- Our approach to the discovery and development of product candidates using our NKp30 platform is unproven and may not result in marketable products.
- 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 delayed timelines.
- 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.
- The loss of our third-party manufacturing partners 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.
- 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.
- 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.
- 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 increases in our financial or other obligations to our licensors.
- 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 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 will need to grow the size of our organization, and we may experience difficulties in managing this growth.

- 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 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.
- 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 resell shares of our common stock at times and prices that you believe are appropriate.
- Our common stock may not be eligible for listing or quotation on any securities exchange.
- 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.
- 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.
- Our business, results of operations and future growth prospects could be materially and adversely affected by the COVID-19 pandemic.

Recent Developments

Reverse Merger

On June 17, 2020, pursuant to an Agreement and Plan of Merger and Reorganization, our wholly-owned subsidiary, Compass Acquisition LLC, a Delaware limited liability company, or the Acquisition Sub, merged with and into Compass OpCo, with Compass OpCo continuing as the surviving entity and our wholly-owned subsidiary, in a transaction which we refer to as the Merger. Additionally, certain of our wholly-owned subsidiaries merged with and into the applicable Blocker entity, or the Blockers, with each Blocker continuing as the surviving entity and our wholly-owned subsidiary, in transactions which we refer to as the Blocker Mergers. As a result of the Merger and the Blocker Mergers, we acquired the business of Compass OpCo, a clinical-stage biotechnology company developing proprietary antibody therapeutics intended to engage the immune system to treat both solid tumors and hematological malignancies. See “Description of Our Business” for more information.

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

Following the closing of the Merger, Olivia Ventures, Inc. changed its name to Compass Therapeutics, Inc.

The Merger and the Blocker Mergers were treated as a recapitalization and reverse acquisition by us for financial reporting purposes. Compass OpCo is considered the acquirer for accounting purposes, and the historical financial statements of Olivia Ventures, Inc. before the Merger will be replaced with the historical financial statements of Compass OpCo 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 Internal Revenue Code of 1986, as amended, or the Code.

Private Placement

On June 19, 2020, we sold 12,096,442 shares of common stock pursuant to the initial closing of a private placement, or the Private Placement, at a purchase price of \$5.00 per share, or the Offering Price.

The initial closing of the Private Placement was conditioned on the closing of the Merger and a minimum aggregate purchase price of \$50.0 million for the shares of common stock sold in the Private Placement, including a minimum of \$10.0 million purchased by certain insider investors introduced by Compass OpCo.

The aggregate gross proceeds from the initial closing of the Private Placement were approximately \$60.5 million (before deducting placement agent fees and total expenses in connection with the initial closing of the Private Placement, which are estimated at approximately \$6.3 million).

The initial closing of the Private Placement was exempt from registration under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated by the SEC thereunder. The common stock in the initial closing of the Private Placement was sold to “accredited investors”, as defined in Regulation D, and was conducted on a “reasonable best efforts” basis.

In connection with the Merger and the Private Placement, we entered into a registration rights agreement, pursuant to which we agreed to file a registration statement on Form S-1 covering 52,127,041 shares of common stock issued in connection with the Merger and the Private Placement. The registration statement was declared effective by the SEC on September 25, 2020.

Emerging Growth Company

We are an “emerging growth company” as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds \$700.0 million as of the prior June 30, if we have total annual gross revenue of approximately \$1.1 billion or more during any fiscal year, or if we issue more than \$1.0 billion in non-convertible debt during any three-year period.

As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise generally applicable to public companies. These provisions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- reduced disclosure about our executive compensation arrangements;
- no requirement that we hold non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We have taken advantage of some of these reduced disclosure and other requirements, and thus the information we provide stockholders may be different than you might receive or obtain from other public companies in which you hold shares.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This permits an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise 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.

Corporate Information

We were originally incorporated in the State of Delaware on March 20, 2018 under the name Olivia Ventures, Inc. Prior to the Merger, Olivia Ventures, Inc. was a “shell” company registered under the Exchange Act, with no specific business plan or purpose until it began operating the business of Compass OpCo following the closing of the Merger on June 17, 2020. Compass OpCo, a clinical-stage biotechnology company developing proprietary antibody therapeutics intended to engage the immune system to treat both solid tumors and hematological malignancies, was originally formed as a private limited liability company under the name Compass Therapeutics, LLC in the State of Delaware on January 29, 2014. As a result of the Merger, we acquired the business of Compass OpCo, and we will continue the existing business operations of Compass OpCo as a public reporting company under the name Compass Therapeutics, Inc.

Our corporate headquarters are located at 245 First Street, 3rd Floor, Cambridge, Massachusetts 02142, and our telephone number is (617) 500-8099. We maintain a website at www.compasstherapeutics.com, where we regularly post copies of our press releases as well as additional information about our company. Our filings with the SEC are available free of charge through the website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Information contained in our website is not a part of, nor incorporated by reference into, this prospectus or our other filings with the SEC, and should not be relied upon.

All trademarks, service marks and trade names appearing in this prospectus are the property of their respective holders. Use or display by us of other parties’ trademarks, trade dress, or products in this prospectus is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

THE OFFERING

Common stock we are offering	9,000,000 shares
Underwriters' option to purchase additional shares	1,350,000 shares
Common stock outstanding after giving effect to this offering	61,120,062 shares

Use of proceeds

We estimate that the net proceeds to us in this offering will be approximately \$45.5 million, or \$52.4 million if the underwriters exercise their option to purchase additional shares in full, after deducting estimated underwriting discounts and commissions, and estimated offering expenses payable by us, based on an assumed public offering price of \$5.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, (i) to fund clinical trials for CTX-471, including a second Phase 1 trial of CTX-471 in combination with Herceptin and/or Erbitux, as well as manufacturing of clinical trial material, and pre-commercialization manufacturing process development and validation, (ii) to advance our other pipeline candidates, including CTX-8371 and CTX-8573, (iii) to fund new and ongoing research activities for our portfolio of bispecific antibody product candidates, and (iv) for working capital purposes, including general operating expenses, to the extent of any remainder amounts.

See "Use of Proceeds" for a more complete description of the intended use of proceeds from this offering.

Risk factors

You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

Proposed Nasdaq Capital Market symbol

CMPX

The number of shares of common stock outstanding is based on an aggregate of 52,120,062 shares outstanding as of September 30, 2020, and excludes 2,930,836 shares of common stock reserved under the 2020 Stock Option and Incentive Plan, or the 2020 Incentive Plan, from which options to purchase an aggregate of 1,625,469 shares of common stock, at an exercise price of \$5.00 per share, have been granted after such date and remain unexercised.

Except as otherwise indicated, all information in this prospectus assumes no exercise by the underwriters of their option to purchase a maximum of 1,350,000 additional shares of common stock from us in this offering at the public offering price, less the underwriting discounts and commissions.

SUMMARY FINANCIAL DATA

The following tables set forth summary financial data as of, and for the nine months ended, September 30, 2020 and 2019, and as of, and for the years ended, December 31, 2019 and 2018, and should be read together with our consolidated financial statements and the related notes, as well as the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” appearing elsewhere in this prospectus. The summary financial data in this section is not intended to replace our financial statements and related notes. The summary consolidated financial data as of, and for the nine months ended, September 30, 2020 and 2019 are derived from our unaudited consolidated financial statements included elsewhere in this prospectus. In our opinion, these unaudited consolidated financial statements have been prepared on a basis consistent with our audited financial statements and contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such consolidated financial data. The summary financial data as of, and for the years ended, December 31, 2020 and 2019 are derived from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of our future results, and our operating results for the nine-month period ended September 30, 2020 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2020 or any other interim periods or any future year or period.

(in thousands except share and per share data)	Nine Months Ended September 30,		Year Ended December 31,	
	2020 (unaudited)	2019 (unaudited)	2019	2018
Statement of Operations Data:				
Operating expenses:				
Research and development expense	\$ 10,498	\$ 19,146	\$ 22,449	\$ 27,095
General and administrative expense	9,364	8,504	11,603	11,217
Total operating expenses	19,862	27,650	34,052	38,312
Operating loss	(19,862)	(27,650)	(34,052)	(38,312)
Other income (expense), net:				
Interest expense	(730)	(944)	(1,228)	(767)
Other income (expense), net	(517)	462	536	793
Total other income/(expense), net	(1,247)	(482)	(692)	26
Net loss	\$ (21,109)	\$ (28,132)	\$ (34,744)	\$ (38,286)
Basic and diluted loss per common share	\$ (0.88)	\$ (4.26)	\$ (5.19)	\$ (6.27)
Basic and diluted weighted average common shares outstanding	23,968,408	6,601,951	6,691,230	6,102,450

	September 30, 2020	
	Actual	As Adjusted ⁽¹⁾ (unaudited)
<i>(in thousands)</i>		
Balance Sheet Data		
Cash and cash equivalents	\$55,518	\$ 101,053
Working capital	48,159	93,810
Total assets	60,690	106,109
Debt (current and noncurrent portions)	11,191	11,191
Total stockholders' equity	47,287	92,822

(1) The as adjusted balance sheet data as of September 30, 2020 gives effect to our receipt of estimated net proceeds from the sale of shares of common stock in this offering at an assumed public offering price of \$5.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions, and estimated offering expenses payable by us. Each \$1.00 increase (decrease) in the assumed public offering price of \$5.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the as adjusted amount of each of cash and cash equivalents, current assets, total current assets and additional paid-in-capital by \$8.4 million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1,000,000 in the number of common shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the as adjusted amount of each of cash and cash equivalents, current assets, total current assets and additional paid-in-capital by \$5.1 million, assuming no change in the assumed public offering price per share.

RISK FACTORS

Investing in our common stock involves a high degree of risk. In addition to the other information set forth in this prospectus, you should carefully consider the risk factors discussed below when considering an investment in our common stock and any risk factors that may be set forth in the applicable prospectus supplement, any related free writing prospectus, as well as the other information contained in this prospectus, any applicable prospectus supplement and any related free writing prospectus. If any of the following risks occur, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that case, the market price of our common stock could decline and you could lose some or all of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

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 \$21.1 million for the nine months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of \$143.0 million. We have funded our operations to date primarily with proceeds from the offering 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.

[Table of Contents](#)

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.

[Table of Contents](#)

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 September 30, 2020, we had \$55.5 million in cash, cash equivalents and marketable securities. 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 first quarter of 2022, 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 initiate IND-enabling activities with respect to our NKp30 bispecific program. 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;

[Table of Contents](#)

- 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.

Table of Contents

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

[Table of Contents](#)

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 the date of this prospectus, 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

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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 immuno-oncology product candidates, including our lead candidate, CTX-471, may have similar or additional side effects. As of September 1, 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 nine 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

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

- 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 or 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;

Table of Contents

- 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

[Table of Contents](#)

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 of 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;

[Table of Contents](#)

- 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

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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, the 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

[Table of Contents](#)

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

[Table of Contents](#)

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.
- 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

[Table of Contents](#)

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 European Union, 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 European Union.

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.

[Table of Contents](#)

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

[Table of Contents](#)

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.

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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 President and 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 Dr. 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

[Table of Contents](#)

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 Blnicyto. 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

[Table of Contents](#)

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.

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.

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;

Table of Contents

- 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.

[Table of Contents](#)

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.

We are an emerging growth company and a smaller reporting 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, and a smaller reporting company under SEC regulations. For as long as we continue to be an emerging growth company and a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies or smaller reporting 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. Notably, 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.

Risks Related to this Offering and Ownership of Our Common Stock

If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

The public offering price of our common stock will be substantially higher than the as adjusted net tangible book value per share of our common stock. Therefore, if you purchase shares of common stock in this offering, you will pay a price per share that substantially exceeds our as adjusted net tangible book value per share after this offering. To the extent shares are subsequently issued under outstanding options, you will incur further dilution. Based on an assumed public offering price of \$5.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$3.98, representing the difference between our as adjusted net tangible book value per share after giving effect to this offering and the public offering price. See the “Dilution” section for a more detailed description of the dilution to new investors in this offering.

[Table of Contents](#)

There is currently no market for our common stock and there can be no assurance that any market will ever develop or that, if one develops, it will be sustained. You may therefore be unable to resell shares of 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. In connection with this offering, we have applied to list our common stock on The Nasdaq Capital Market under the symbol “CMPX”. We cannot assure you that, even if our common stock is approved for listing on The Nasdaq Capital Market, we will be able to maintain compliance with its listing requirements, which could ultimately result in our common stock being de-listed. Additionally, there can be no assurance that any market for our common stock will ever develop or that, if it develops, will be sustained. Accordingly, you may experience difficulty in reselling your shares at times and prices that you may desire.

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.

In connection with this offering, we have applied to list our common stock on The Nasdaq Capital Market. If our common stock is approved for listing and a market for our common stock develops, the market price of our common stock 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;

Table of Contents

- 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 September 30, 2020, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 82.6% of our common stock, including restricted stock. In addition, certain of our principal stockholders, including stockholders affiliated with certain of our directors, have indicated an interest in purchasing a substantial amount of the shares of our common stock offered in this offering at the public offering price and on the same terms and conditions as the other purchasers in this offering. 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.

If securities or industry analysts do not publish research or reports about our business, or they publish negative reports about our business, our share price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares or publish negative views on us or our shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Future resales of our common stock 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. In the event a public market for our common stock develops and is sustained in the future, sales of our common stock may be made by holders of our public float or by holders of restricted securities in compliance with the provisions of Rule 144 of the Securities Act. Under Rule 144, sales of the securities of a former shell company, such as us, are not permitted (i) until at least 12 months have elapsed from June 23, 2020, the filing date of our Current Report on Form 8-K reflecting our status as a non-shell company, and (ii) unless at the time of a proposed sale, we are subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act and have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Exchange Act, as applicable, during the preceding 12 months, other than Current Reports on Form 8-K. We are currently a “voluntary filer” and are not subject to the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. As a result, unless we register shares subject to Rule 144 for sale under the Securities Act, our stockholders will be forced to hold their shares of common stock for at least that 12-month period before they are eligible to sell those shares, and even after that 12-month period, sales may not be made under Rule 144 unless we and any selling stockholders are in compliance with other requirements of Rule 144.

Future sales of shares of our public float or by holders of restricted common stock made in compliance with Rule 144 may have an adverse effect on the then prevailing market price, if any, of our common stock.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have 61,120,062 shares of common stock outstanding based on the number of shares outstanding as of September 30, 2020. Shares issued and sold in this offering may be resold in the public market immediately without restriction, unless purchased by our affiliates, officers, directors and certain stockholders subject to Rule 144 under the Securities Act or lock-up agreements. Any shares purchased by our existing stockholders through the underwriters in this offering would not be subject to these lock-up agreements. A significant portion of our shares outstanding prior to the completion of this offering will be subject to lock-up agreements as described in “Underwriting”. If, after the end of such lock-up agreements, these stockholders sell substantial amounts of our securities in the public market, or the market perceives that such sales may occur, the market price of our shares and our ability to raise capital through an issuance of equity securities in the future could be adversely affected.

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.

[Table of Contents](#)

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 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 maintain 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 to 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 to 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 need to engage 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.

Our management team has broad discretion in the use of our cash resources, and may not use them effectively.

We currently intend to use our cash resources 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,

[Table of Contents](#)

the advancement of our second product candidate, CTX-8371, into IND-enabling studies, which were initiated in August 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 our cash resources in such a manner, our management team will have broad discretion with respect to their use. Accordingly, investors will need to rely on our judgment with respect to these proceeds.

We cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. In addition, the amount, allocation and timing of our actual expenditures will depend upon numerous factors, many of which are beyond our control. 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 our cash resources 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

[Table of Contents](#)

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 favorable 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 from 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 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.

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.

USE OF PROCEEDS

We estimate that the net proceeds to us in this offering will be approximately \$45.5 million, or \$52.4 million if the underwriters exercise their option to purchase additional shares in full, after deducting estimated underwriting discounts and commissions, and estimated offering expenses payable by us, based on an assumed public offering price of \$5.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

Each \$1.00 increase (decrease) in the assumed public offering price of \$5.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by \$8.4 million, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1,000,000 in the number of shares of common stock offered would increase (decrease) the net proceeds to us from this offering by \$5.1 million, assuming the assumed public offering price remains the same.

We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, (i) to fund clinical trials for CTX-471, including a second Phase 1 trial of CTX-471 in combination with Herceptin and/or Erbitux, as well as manufacturing of clinical trial material, and pre-commercialization manufacturing process development and validation, (ii) to advance our other pipeline candidates, including CTX-8371 and CTX-8573, (iii) to fund new and ongoing research activities for our portfolio of bispecific antibody product candidates, and (iv) for working capital purposes, including general operating expenses, to the extent of any remainder amounts.

Our expected use of the net proceeds from this offering reflects our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We cannot predict with certainty all of the particular uses for the net proceeds from this offering. Predicting the costs necessary to develop product candidates can be difficult. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our current plans, we believed that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to enable us to fund our operations and capital expenditure requirements through the third quarter of 2022. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Pending our use of proceeds from this offering, we plan to invest these net proceeds in a variety of capital preservation instruments, including short-term, interest bearing obligations and investment-grade instruments. We cannot predict whether such investments will yield a favorable return.

DIVIDEND POLICY

We currently intend to retain future earnings, if any, to maintain and expand our operations. We have never declared or paid cash dividends on our common stock and we do not intend to pay any cash dividends on our common stock for the foreseeable future. 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. Any future determination related to our dividend policy will be made at the discretion of our board of directors in light of conditions then-existing, including factors such as our results of operations, financial condition and requirements, business conditions and covenants under any applicable contractual arrangements.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2020 on:

- an actual basis; and
- on an as adjusted basis to give further effect to the issuance and sale of 9,000,000 shares of common stock in this offering.

The as adjusted calculations assume a public offering price of \$5.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The as adjusted information presented below is illustrative only and our capitalization following this offering will change based on the actual public offering price and any other terms of this offering determined at pricing. You should read this information together with our audited consolidated financial statements and related notes appearing elsewhere in this prospectus and the information set forth in the sections titled “Use of Proceeds” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

	As of September 30, 2020	
	Actual (Unaudited)	As Adjusted ⁽¹⁾
(In thousands, except share and per share data)		
Cash and cash equivalents	\$ 55,518	\$ 101,053
Long-term debt (including current portion)	\$ 11,191	\$ 11,191
Stockholders' equity:		
Common stock, \$0.0001 par value; 300,000,000 shares authorized, 52,120,062 shares issued and outstanding, actual; 61,120,062 shares issued and outstanding, as adjusted	\$ 5	\$ 6
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding, actual and as adjusted	—	—
Additional paid in capital	190,299	235,833
Accumulated deficit	(143,017)	(143,017)
Total stockholders' equity	\$ 47,287	\$ 92,822
Total capitalization	\$ 58,478	\$ 104,013

- (1) Each \$1.00 increase (decrease) in the assumed public offering price of \$5.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the as adjusted amount of each of cash and cash equivalents, total shareholders' equity and total capitalization by \$8.4 million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1,000,000 in the number of common shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the as adjusted amount of each of cash and cash equivalents, total shareholders' equity and total capitalization by \$5.1 million, assuming no change in the assumed public offering price per share.

The number of shares of common stock outstanding is based on an aggregate of 52,120,062 shares outstanding as of September 30, 2020, and excludes 2,930,836 shares of common stock reserved under the 2020 Incentive Plan, from which options to purchase an aggregate of 1,625,469 shares of common stock, at an exercise price of \$5.00 per share, have been granted after such date and remain unexercised.

DILUTION

If you invest in our shares of common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the public offering price per share in this offering and the as adjusted net tangible book value per share after this offering. As of September 30, 2020, we had a historical net tangible book value of \$47.2 million, or \$0.91 per share of common stock. Our net tangible book value per share represents total tangible assets less total liabilities, divided by the number of shares of common stock outstanding on September 30, 2020.

After giving effect to the sale of 9,000,000 shares in this offering at an assumed public offering price of \$5.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value at September 30, 2020 would have been \$1.52 per share. This represents an immediate increase in as adjusted net tangible book value of \$0.61 per share to new investors and immediate dilution of \$3.98 per share to new investors. The following table illustrates this dilution to new investors purchasing shares of common stock in this offering:

Assumed public offering price per share	\$ 5.50
Historical net tangible book deficit per share as of September 30, 2020	0.91
Increase in as adjusted net tangible book value per share attributable to new investors purchasing shares in this offering	<u>0.61</u>
As adjusted net tangible book value per share after this offering	<u>1.52</u>
Dilution per share to new investors purchasing shares in this offering	<u>\$ 3.98</u>

The as adjusted information is illustrative only and will change based on the actual public offering price and other terms of this offering determined at pricing. Each \$1.00 increase (decrease) in the assumed public offering price of \$5.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our as adjusted net tangible book value after this offering by \$0.14 per share, and would increase (decrease) dilution to new investors by \$0.86 per share, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1,000,000 in the number of common shares we are offering would increase (decrease) our as adjusted net tangible book value after this offering by \$0.06 per share, and would increase (decrease) dilution to new investors by \$0.06 per share, based on the assumed public offering price per share.

If the underwriters exercise their option to purchase additional common shares in full, the as adjusted net tangible book value per share would be \$1.60, the increase in net tangible book value per share to existing shareholders would be \$0.69 and the immediate dilution in net tangible book value per share to new investors in this offering would be \$3.90, assuming a public offering price of \$5.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

[Table of Contents](#)

The following table summarizes, on an as adjusted basis giving effect to the sale of 9,000,000 shares of common stock in this offering at an assumed public offering price of \$5.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, the differences between the existing shareholders and the new investors in this offering with respect to the number of shares purchased from us, the total consideration paid to us and the average price per share, based on an assumed public offering price of \$5.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	<u>Shares Purchased</u>		<u>Total Consideration</u>		<u>Average Price Per Share</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	
Existing shareholders(1)	52,120,062	85%	\$192,522	80%	\$ 3.69
New investors purchasing common shares in this offering	9,000,000	15	49,500	20	\$ 5.50
Total	<u>61,120,062</u>	<u>100.0%</u>	<u>\$242,022</u>	<u>100.0%</u>	

(1) Certain of our principal stockholders, including stockholders affiliated with certain of our directors, have indicated an interest in purchasing a substantial amount of the shares of our common stock offered in this offering at the public offering price and on the same terms and conditions as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discounts and commissions on any shares purchased by these parties as they will on any other shares sold to the public in this offering.

Each \$1.00 increase (decrease) in the assumed public offering price of \$5.50 per share, which is the midpoint of the price range on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by \$8.4 million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by three percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by three percentage points, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1,000,000 in the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by \$5.1 million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by two percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by two percentage points, assuming no change in the assumed public offering price per share.

If the underwriters exercise their option to purchase additional common shares in full, the percentage of shares held by existing shareholders will decrease to 83% of the total number of shares outstanding after the offering, and the number of shares held by new investors will be increased to 10,350,000, or 17% of the total number of shares outstanding after this offering.

The table and discussion above are based on an aggregate of 52,120,062 shares outstanding as of September 30, 2020, and exclude 2,930,836 shares of common stock reserved under the 2020 Incentive Plan, from which options to purchase an aggregate of 1,625,469 shares of common stock, at an exercise price of \$5.00 per share, have been granted after such date and remain unexercised. To the extent that shares of common stock are issued under the 2020 Incentive Plan or we issue additional shares of common stock in the future, there will be further dilution to our existing shareholders and investors participating in this offering.

DESCRIPTION OF THE MERGER, THE PRIVATE PLACEMENT AND RELATED TRANSACTIONS

Reverse Merger

On June 17, 2020, pursuant to an Agreement and Plan of Merger and Reorganization, our wholly-owned subsidiary, the Acquisition Sub, merged with and into Compass OpCo, with Compass OpCo continuing as the surviving entity and our wholly-owned subsidiary, in the Merger. Additionally, certain of our wholly-owned subsidiaries merged with and into the applicable Blocker, with each Blocker continuing as the surviving entity and our wholly-owned subsidiary, in the Blocker Mergers. As a result of the Merger and the Blocker Mergers, we acquired the business of Compass OpCo, a clinical-stage biotechnology company developing proprietary antibody therapeutics intended to engage the immune system to treat both solid tumors and hematological malignancies. See “Description of Our Business” for more information.

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

Following the closing of the Merger, Olivia Ventures, Inc. changed its name to Compass Therapeutics, Inc.

The Merger and the Blocker Mergers were treated as a recapitalization and reverse acquisition by us for financial reporting purposes. Compass OpCo is considered the acquirer for accounting purposes, and the historical financial statements of Olivia Ventures, Inc. before the Merger will be replaced with the historical financial statements of Compass OpCo 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.

The Merger Agreement contained customary representations and warranties and pre- and post-closing covenants of each party and customary closing conditions. As a condition to the Merger, we entered into an indemnity agreement with our former officers and directors, or the Pre-Merger Indemnity Agreement, pursuant to which we agreed to indemnify such former officers and directors for actions taken by them in their official capacities relating to the consideration, approval and consummation of the Merger and certain related transactions. The form of the Pre-Merger Indemnity Agreement is filed as an exhibit to the registration statement of which this prospectus forms a part. All descriptions of the Pre-Merger Indemnity Agreement herein are qualified in their entirety by reference to the text thereof filed as an exhibit hereto, which is incorporated herein by reference.

The Private Placement

On June 19, 2020, we sold 12,096,442 shares of common stock pursuant to the initial closing of a private placement, or the Private Placement, at an offering price of \$5.00 per share, or the Offering Price.

The aggregate gross proceeds from the initial closing of the Private Placement were approximately \$60.5 million (before deducting placement agent fees and total expenses in connection with the initial closing of the Private Placement, which are estimated at approximately \$6.3 million).

The initial closing of the Private Placement was exempt from registration under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated by the SEC thereunder. The common stock in the

[Table of Contents](#)

initial closing of the Private Placement was sold to “accredited investors”, as defined in Regulation D, and was conducted on a “reasonable best efforts” basis.

The initial closing of the Private Placement was conditioned on the closing of the Merger and a minimum aggregate purchase price of \$50.0 million for the shares of common stock sold in the Private Placement, including a minimum of \$10.0 million purchased by certain insider investors introduced by Compass OpCo.

In connection with the Private Placement, we paid the Placement Agents an aggregate commission of approximately \$4.7 million and reimbursed the Placement Agents for approximately \$75 thousand of expenses.

Subject to certain customary exceptions, we have agreed to indemnify the Placement Agents to the fullest extent permitted by law against certain liabilities that may be incurred in connection with the Private Placement, including certain civil liabilities under the Securities Act, and, where such indemnification is not available, to contribute to the payments the Placement Agents and their sub-agents may be required to make in respect of such liabilities.

The descriptions of the Agreement and Plan of Merger and Reorganization and the subscription agreements in connection with the Private Placement are qualified in their entirety by reference to the terms of such agreements, which are filed as exhibits to the registration statement of which this prospectus forms a part, and are incorporated by reference herein.

In connection with the Merger and the Private Placement, we entered into a registration rights agreement, pursuant to which we agreed to file a registration statement on Form S-1 covering 52,127,041 shares of common stock issued in connection with the Merger and the Private Placement. The registration statement was declared effective by the SEC on September 25, 2020.

DESCRIPTION OF OUR 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. The dose escalation stage of the Phase 1 trial has been completed and the dose expansion stage has been initiated, with the first patient dosed in September 2020. We aim to complete the Part 2 cohort expansion portion of the trial by the second half of 2021 and to initiate a Phase 2/3 trial of CTX-471 by early 2022.

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. We aim to submit an IND application for CTX-471 in combination with trastuzumab by early 2021 and are targeting the first patient first visit in the first half of 2021. We expect to generate top-line data from the Phase 1b trial of CTX-471 in combination with trastuzumab in the first half of 2022.

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™ 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

[Table of Contents](#)

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 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. IND-enabling studies with CTX-8371 were initiated in August 2020. We are targeting our second IND submission for CTX-8371 in the third quarter of 2021 and our first patient first visit in the second half of 2021. We aim to deliver early safety and top-line data in 2022.

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 \hat{I} 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% to 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. We aim to make our third IND submission for CTX-8573 in late 2021 or early 2022 and to enter clinic by early 2022.

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 OpCo, Dr. Schuetz was a venture partner with OrbiMed Advisors LLC where he participated in OrbiMed's investments in Enobia Pharma (sold to Alexion), Relypsa (sold to Galenica), Artea 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 President and Chief Operating Officer, Vered Bisker-Leib, Ph.D., M.B.A., has over 18 years of experience in strategy, business development, finance and operations of biotechnology and pharmaceutical companies. Prior to joining Compass Therapeutics LLC, 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. and other biotech companies focused on therapies addressing rare diseases and served as

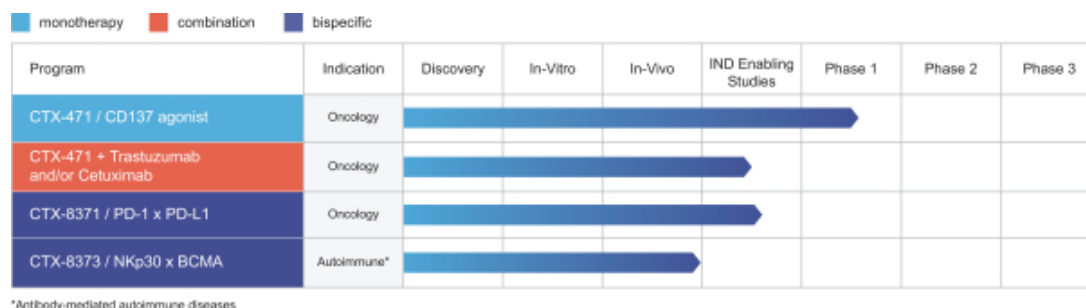
Table of Contents

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 preclinical programs: CTX-8371 and CTX-8573.



Our 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 at least 3 months of stable disease on prior checkpoint therapies. We expect to report data from Part 2, the dose expansion part of the trial, of the Phase 1 trial in the first half of 2021. The dose escalation portion of the Phase 1 trial is complete. We aim to complete the Part 2 cohort expansion portion of the trial by the second half of 2021 and to initiate a Phase 2/3 trial of CTX-471 by early 2022. In addition, we aim to submit an IND application for CTX-471 in combination with trastuzumab by early 2021 and are targeting the first patient first visit in the first half of 2021. We expect to generate top-line data from the Phase 1b trial of CTX-471 in combination with trastuzumab in the first half of 2022.
- **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. IND-enabling studies with CTX-8371 were initiated in August 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 deplete 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.

[Table of Contents](#)

- **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 clinical development expertise 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 a 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

Table of Contents

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.

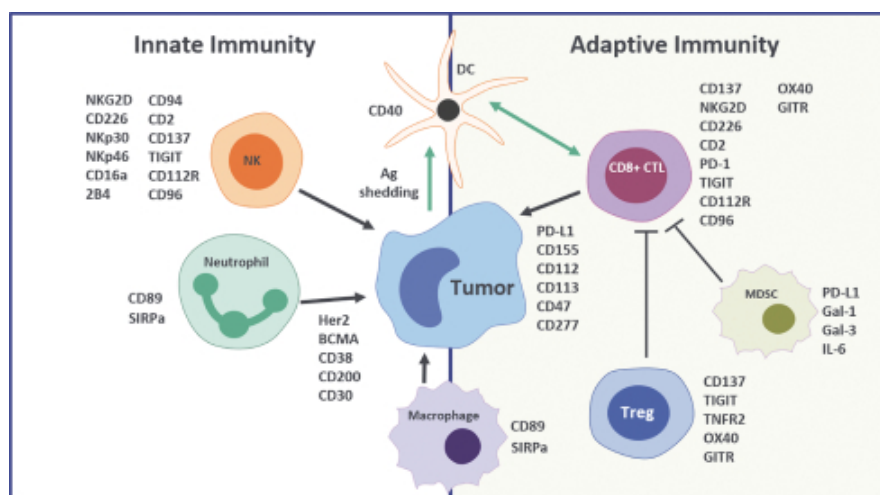


Figure 1. We have discovered proprietary antibodies that modulate two key components of the immune system: innate immunity and adaptive immunity. These antibodies bind to different cells of the immune system, and enhance its activities. In addition, we have discovered proprietary antibodies to selected 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™ 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™ 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™ screening candidate bispecifics into bispecific antibody product candidates.

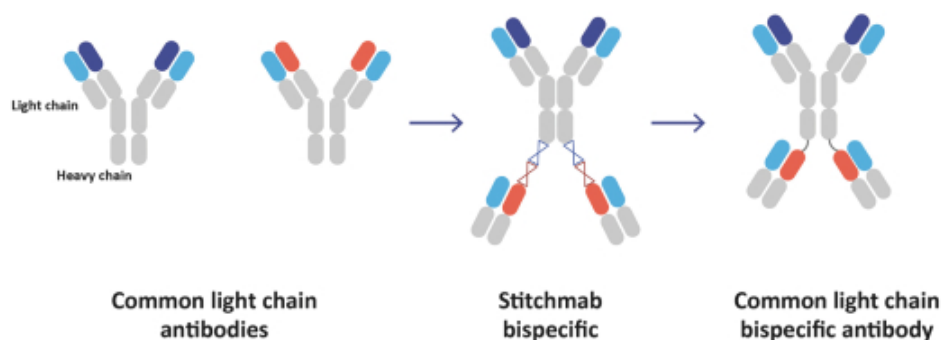


Figure 2. A common light chain simplifies the production of bispecific antibodies

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 followed by a dose expansion cohort. The dose escalation stage of the Phase 1 trial has been completed, and the dose expansion stage has been initiated, with the first patient dosed in September 2020.

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.

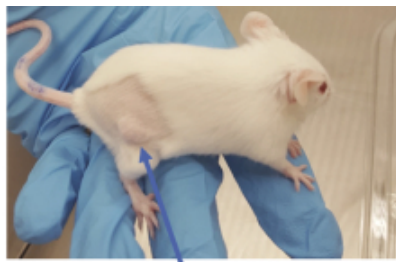
Our solution, CTX-471

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 γ RI and Fc γ RIIb to facilitate CD137 cross-linking while avoiding binding to Fc γ RIIIa and depletion of immune effector cells through ADCC.

Identification through functional screening

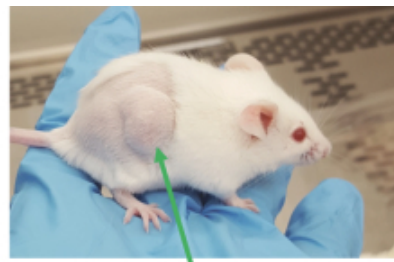
We evaluated a panel of anti-CD137 antibodies as potential candidates for CTX-471 and used a series of *in vitro* and *in vivo* functional assays to screen for the best candidate. One of the most stringent assays was antitumor activity in a CT26 mouse colon carcinoma model in which tumors were allowed to grow to 500 mm³ 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.



Small CT26 tumor: ~75 mm³

- Typical size at which treatment begins in mouse efficacy studies



Large CT26 tumor: ~500 mm³

- Treating extremely large tumors of this size is generally considered futile

Figure 3. Preclinical antitumor activity evaluation of CTX-471 was conducted in mice with 500 mm³ 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.

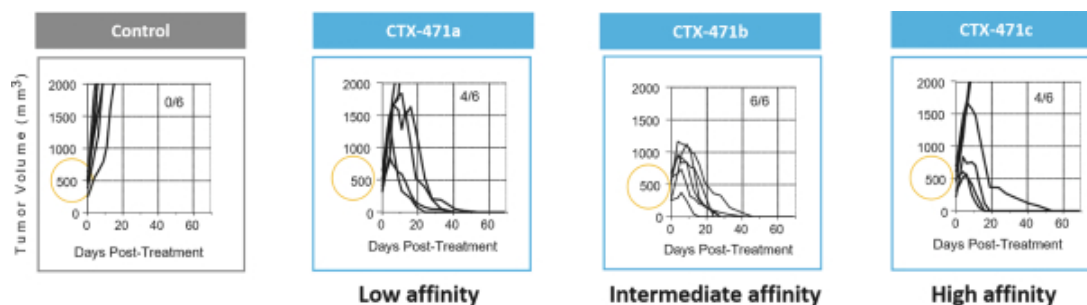


Figure 4. CTX-471a, CTX-471b and CTX-471c are three CD137 agonistic antibodies with low, intermediate and high affinity to CD137 respectively. Four groups of CT-26 syngeneic mice models were dosed with control antibody, CTX-471a, CTX-471b and CTX-471c. Treatment initiated when tumors reached 500 mm³. 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.

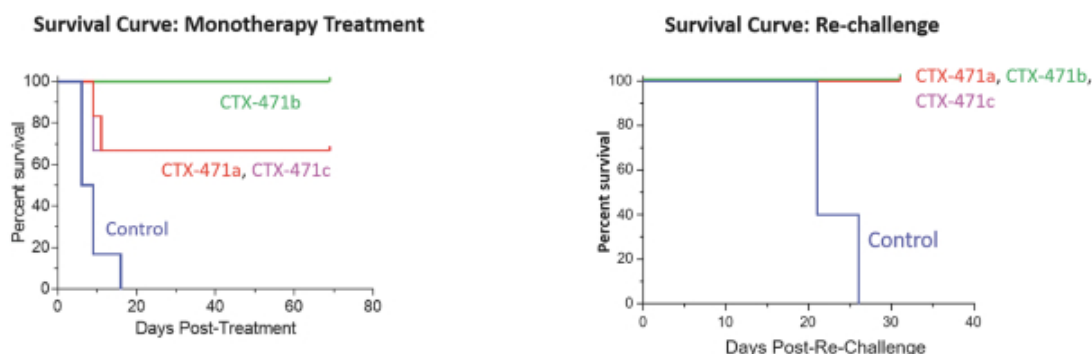


Figure 5. All mice cured by CTX-471 treatment have been resistant to re-challenge with the same tumor

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.

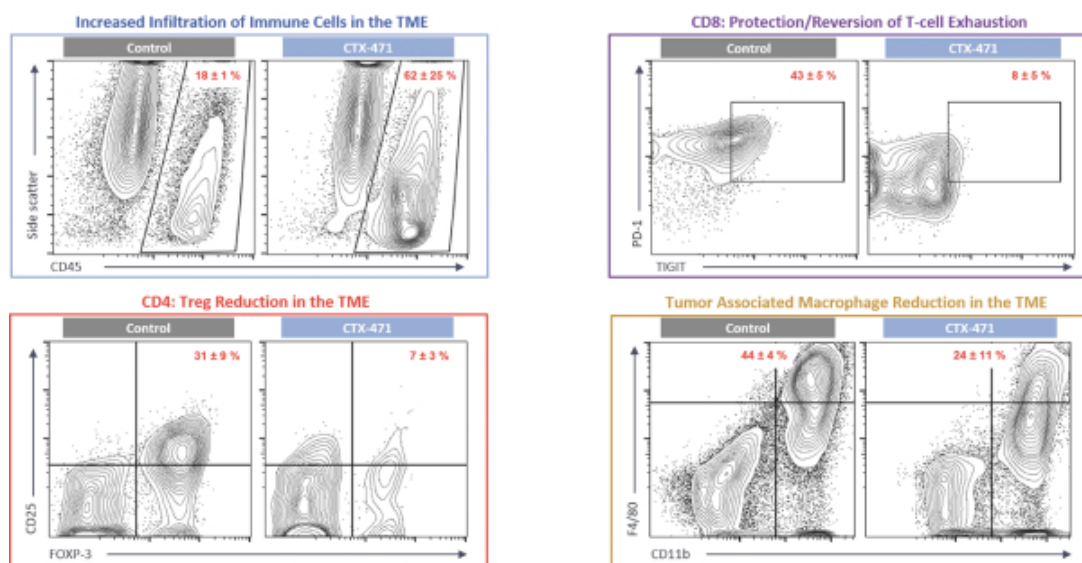


Figure 6. CTX-471 altered the immune composition in the tumor microenvironment

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 has 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

Table of Contents

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.

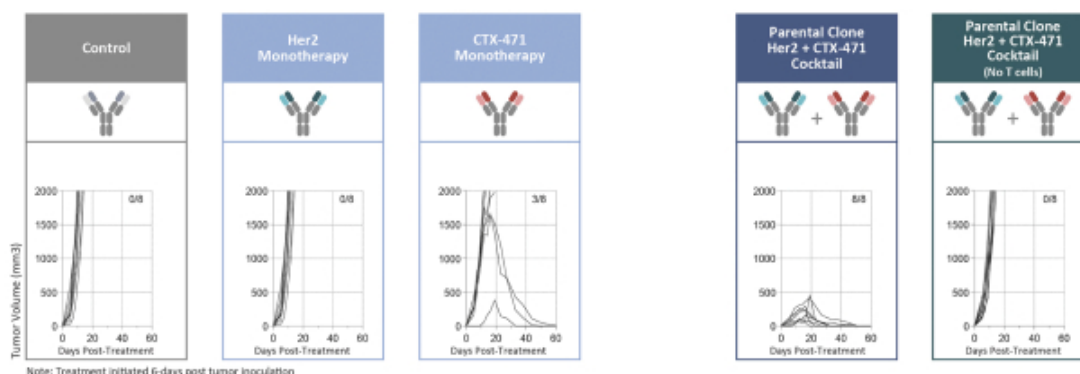


Figure 7. Treatment with a combination of CTX-471 with trastuzumab led to complete eradication of CT26 tumors expressing Her2

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. The dose escalation stage of the Phase 1 trial has been completed and the dose expansion stage has been initiated, with the first patient dosed in September 2020.

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

[Table of Contents](#)

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.

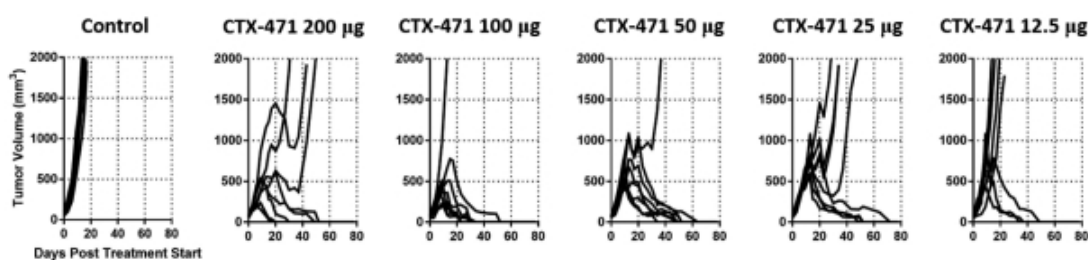


Figure 8. Antitumor activity of CTX-471 is optimized at intermediate dose and decreased at the highest dose level

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

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.

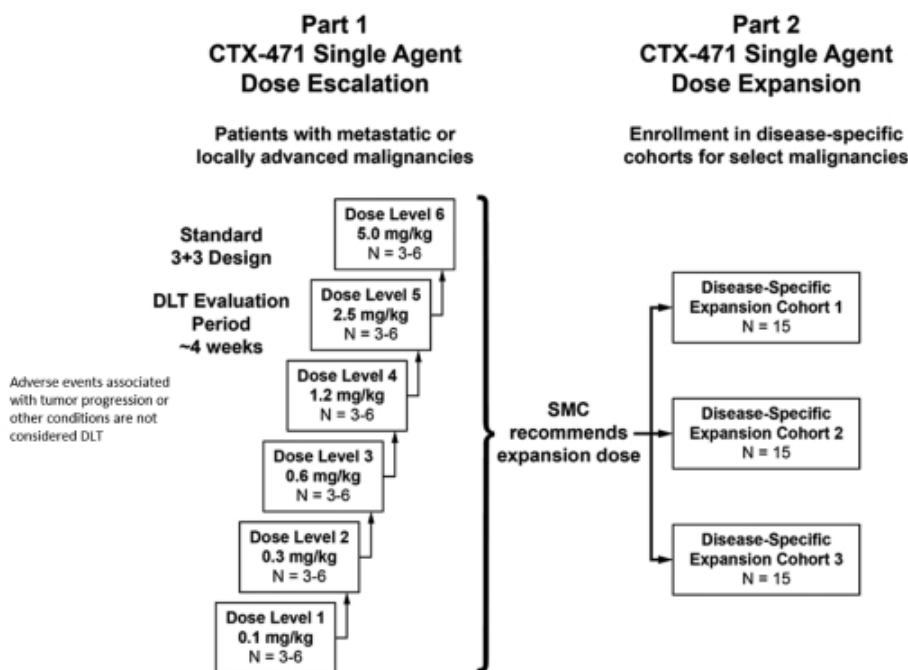


Figure 9. Design of the multiple ascending dose escalation Phase 1 trial of CTX-471

As of September 1, 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 0.1 mg/kg	Cohort 0.3 mg/kg	Cohort 0.6 mg/kg	Cohort 1.2 mg/kg	Total
Enrolled	3	3	6	7	19

Figure 10. The number of patients dosed with CTX-471 as of September 1, 2020

CTX-471 has been observed to be generally well-tolerated. There have been nine 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 trial 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 trial have been evaluated every eight weeks by imaging techniques, such as MRI or CT, until disease progression or withdrawal from the trial, in order to collect such data.

[Table of Contents](#)

All nineteen patients who have been enrolled in the trial have completed Part 1. None of the patients enrolled in the Part 1 of the trial had a complete response or a partial response by RECIST. The best overall response has been stable disease. Two patients with NSCLC had stable disease until progression at Weeks 25 and 41, respectively. That patient had an approximately 24% decline in the total size of his measured metastatic tumors (target lesions) at week 33.

We have preliminary pharmacokinetic data from the trial 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%.

The dose escalation stage of the Phase 1 trial has been completed, and the dose expansion stage has been initiated, with the first patient dosed in September 2020. In the second half of 2020 and the first half of 2021, 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 228,000 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. There are approximately 90,000 patients with advanced/metastatic NSCLC per year who are in great need of pharmacological treatment.

Table of Contents

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 depicted in the diagram below.

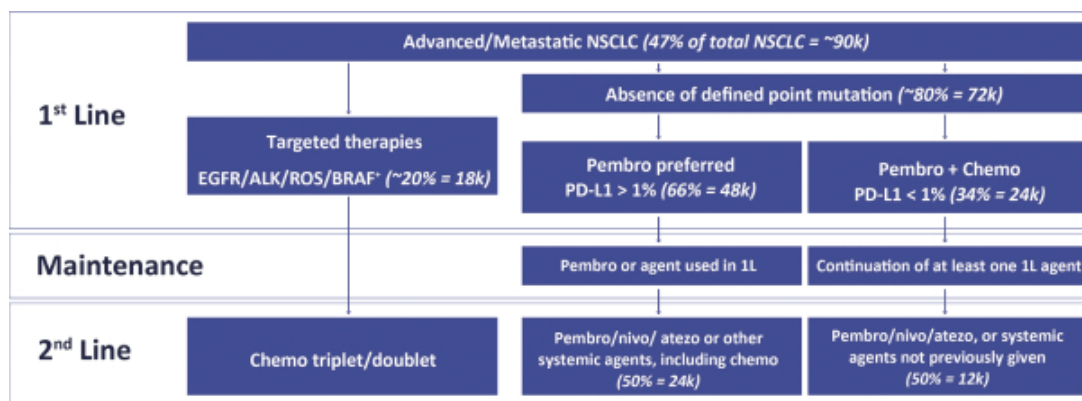


Figure 11. Estimate of the number of treatment-eligible advanced/metastatic NSCLC patients based on NCCN guidelines and other Compass analysis.

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. Preclinical studies demonstrate that CTX-8371 has the ability to outperform 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. IND-enabling studies on CTX-8371 were initiated in August 2020.



Figure 12. 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 \$22 billion. There is no approved 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™ 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™ 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.

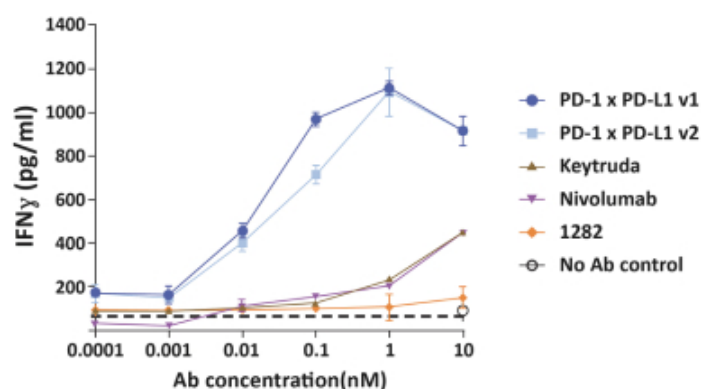


Figure 13. A PD-1 x PD-L1 bispecific antibody outperformed PD-1 antibodies in a T-cell activation assay

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;

Table of Contents

- 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.

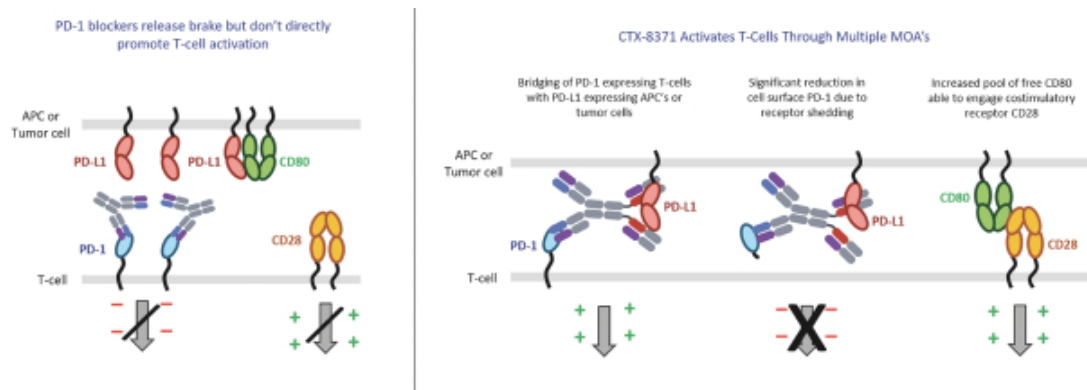


Figure 14. Differentiated mechanism of action of CTX-8371 drives enhanced T-cell activation

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 activity 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.

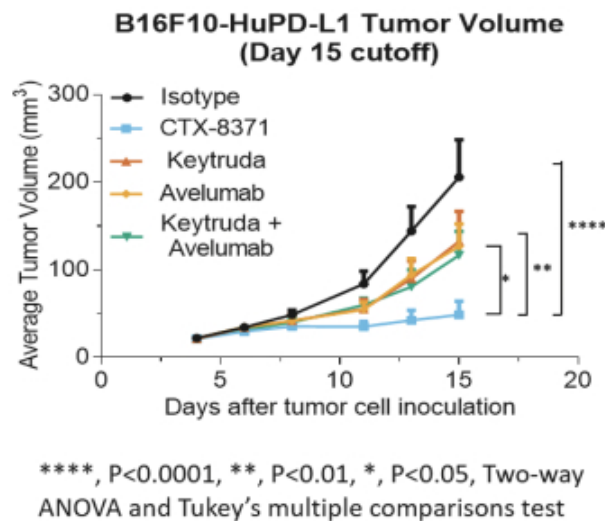


Figure 15. Tumor growth inhibition was improved when treating mice with CTX-8371 compared to treating them with monoclonal antibodies that inhibited either PD-1, PD-L1, or the combination of PD-1 and PD-L1

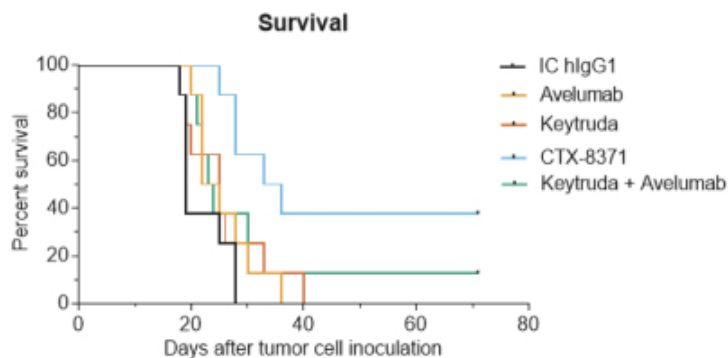


Figure 16. Dosing with CTX-8371 led to improved overall survival in a B16F10 melanoma model compared to either PD-1- or PD-L1- checkpoint inhibitors or to the combination of both

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.

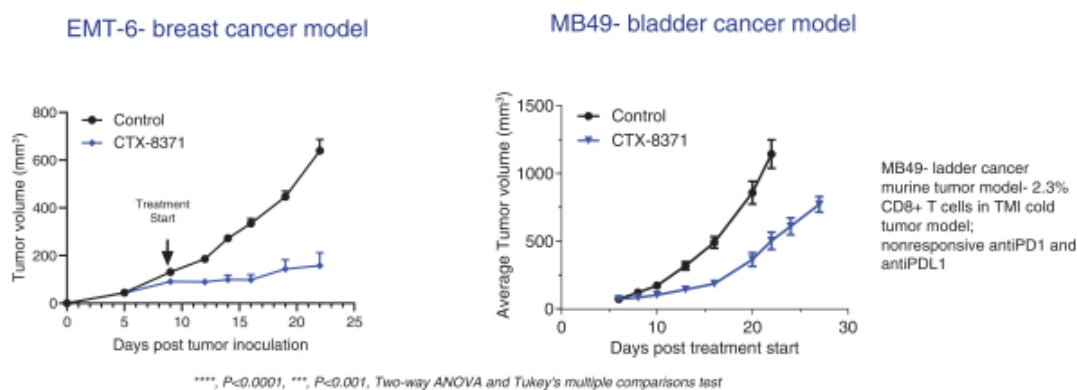


Figure 17. Dosing with CTX-8371 led to tumor growth inhibition in the syngeneic EMT-6 breast cancer model and in the syngeneic MB49 bladder cancer model

IND-enabling studies with CTX-8371 were initiated in August 2020 with the goal of initiating its clinical testing in the second half of 2021 following submission and acceptance 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™ 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 screening led us to the identification of the 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

[Table of Contents](#)

receptor on NK cells and on a subset of T-cells called gamma delta T-cells or gd T-cells. Stimulation of NKp30 leads to activation of NK cell and gd-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 Fc γ R3 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.

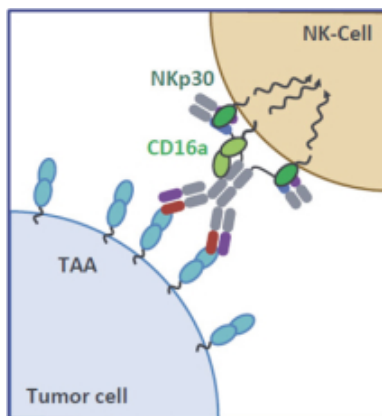


Figure 18. Proposed mechanism of NKp30 bispecific directed tumor cell killing

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 to IND-enabling studies. 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 19. 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 the 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 the killing of cells not expressing BCMA.

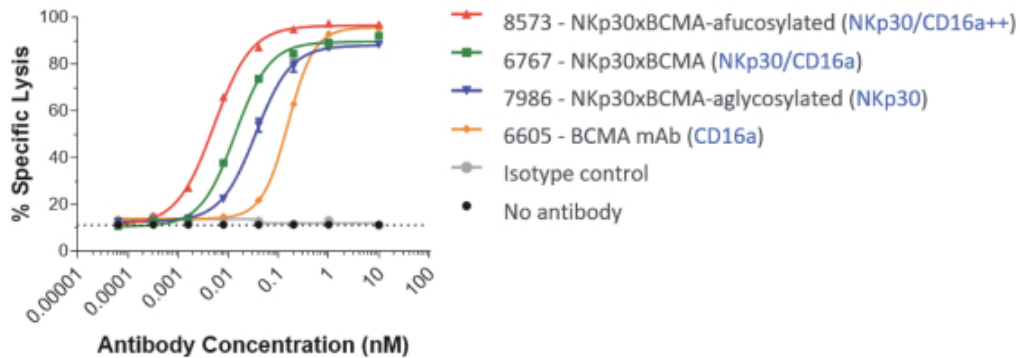


Figure 20. CTX-8573 killed H929 tumor cells with a potency approximately twenty-fold higher than that of a BCMA antibody

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.

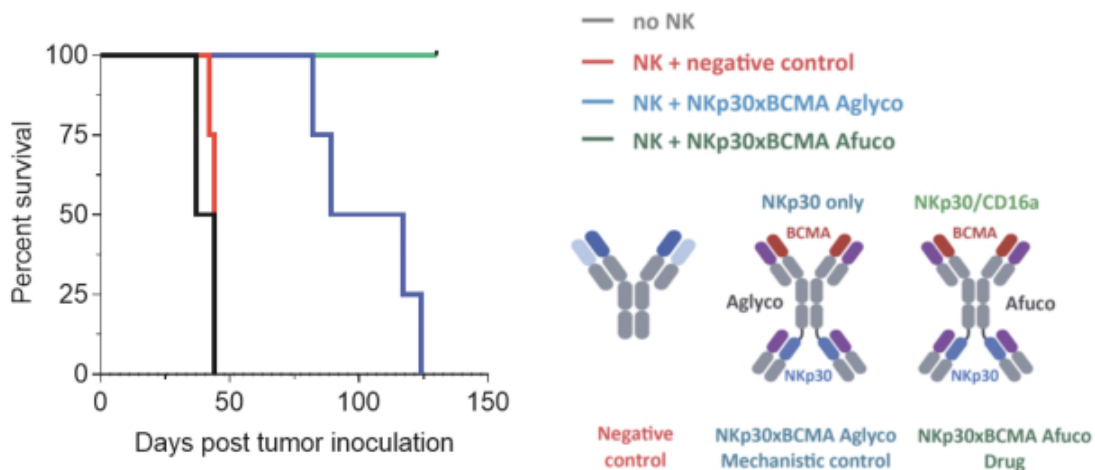


Figure 21. Treatment with CTX-8573 led to long-term survival in a H929 tumor model

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.

[Table of Contents](#)

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.

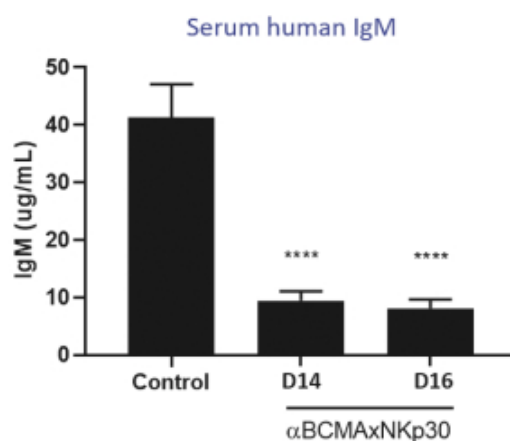


Figure 22. CTX-8573 leads to significant reductions in serum levels of human IgM

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 observed 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 in 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.

[Table of Contents](#)

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 63 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 six patents which have issued in the United States related to our CTX-471 program.

We own six pending patent families with six issued U.S. patents, four 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 10 pending patent families with 12 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

[Table of Contents](#)

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, six pending patent families with five U.S. Utility or provisional patent applications and four PCT patent applications related to our discovery and research programs. Patents that grant from these patent families are generally expected to start to expire in 2039, subject to possible patent term extension.

We own four pending patent families with two U.S. Utility or provisional patent applications and two PCT patent applications 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 OpCo 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.

[Table of Contents](#)

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 Kadcyła, 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 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 also 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,

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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 application fee 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

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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 PHS Act 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

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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, under the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, the 2% Medicare sequestration 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, 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.

[Table of Contents](#)

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 became effective as of January 1, 2019. Although a number of these, and other measures may require additional authorization to become effective, Congress and the Trump administration have indicated that they 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,

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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 European Union, 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 European Union.

Employees

As of September 30, 2020, we had 29 employees, of which 28 were full-time employees, 19 were primarily engaged in research and development activities and 15 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 OpCo, a private limited liability company formed on January 29, 2014. Following the Merger, Compass OpCo was the surviving entity and became our wholly-owned subsidiary, and all of the outstanding common and preferred membership interests of Compass OpCo 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 OpCo and we will continue the existing business operations of Compass OpCo 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.

[Table of Contents](#)

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.

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 prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, 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 "Special Note Regarding Forward-Looking Statements" elsewhere in this prospectus. You should review the disclosure under the heading "Risk Factors" in this prospectus 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 long as their continued development is 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 our equity securities and borrowings under the 2018 Compass LLC Credit Facility. Through September 30, 2020, we had received gross proceeds of \$132.0 million from the sale of Compass Therapeutics equity securities, \$15.0 million under the 2018 Compass LLC Credit Facility and \$60.5 million in gross proceeds (\$54.2 in net proceeds) from the sale of our common stock in a private placement.

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 \$21.1 million and \$28.1 million for the nine months ended September 30, 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, 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 September 30, 2020, we had

[Table of Contents](#)

\$55.5 million in cash, cash equivalents and marketable securities. 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 first quarter of 2022, 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 initiate IND-enabling activities with respect to our NKp30 bispecific program. 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, our wholly-owned subsidiary, Compass Acquisition LLC, a Delaware limited liability company, or the Acquisition Sub, merged with and into Compass OpCo, with Compass OpCo continuing as the surviving entity and our wholly-owned subsidiary, in a transaction which we refer to as the Merger. Additionally, certain of our wholly-owned subsidiaries merged with and into the applicable Blockers, with each Blocker continuing as the surviving entity and our wholly-owned subsidiary, in transactions which we refer to as the Blocker Mergers. As a result of the Merger and the Blocker Mergers, we acquired the business of Compass OpCo.

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

Following the closing of the Merger, Olivia Ventures, Inc. changed its name to Compass Therapeutics, Inc.

The Merger and the Blocker Mergers were treated as a recapitalization and reverse acquisition by us for financial reporting purposes. Compass OpCo is considered the acquirer for accounting purposes, and the historical financial statements of Olivia Ventures, Inc. before the Merger will be replaced with the historical financial statements of Compass OpCo 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.

The issuance of securities pursuant to the Share Conversion was not registered under the Securities Act, in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act, which exempts transactions by an issuer not involving any public offering, and Rule 506 of Regulation D promulgated by the SEC thereunder. These securities may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirement, and are subject to further contractual restrictions on transfer as described under “Market Price of and Dividends on the Registrant’s Common Equity and Related Stockholder Matters”.

The Private Placement

On June 19, 2020, we sold 12,096,442 shares of common stock pursuant to the initial closing of the offering, or the Offering, at a purchase price of \$5.00 per share, or the Offering Price.

The initial closing of the Offering was conditioned on the closing of the Merger and a minimum aggregate purchase price of \$50.0 million for the shares of common stock sold in the Offering, including a minimum of \$10.0 million purchased by certain insider investors introduced by Compass OpCo.

The aggregate gross proceeds from the initial closing of the Offering were approximately \$60.5 million (before deducting placement agent fees and total expenses in connection with the initial closing of the Offering, which are estimated at approximately \$6.3 million).

The initial closing of the Offering was exempt from registration under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated by the SEC thereunder. The common stock in the initial closing of the Offering was sold to “accredited investors”, as defined in Regulation D, and was conducted on a “reasonable best efforts” basis.

COVID-19 Update

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, 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 from mid-March 2020 to mid-May 2020, while ensuring essential staffing levels at our operations remain in place, including maintaining key personnel in our laboratory facilities. Since mid-May 2020, we have initiated a gradual process of returning back to work, including implementation of stringent safety measures designed to create safe and clean environment for our employees as we continue to comply with all 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.

[Table of Contents](#)

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.

[Table of Contents](#)

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 OpCo, 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 OpCo are recorded in our consolidated financial statements. The wholly-owned subsidiary of Compass OpCo, 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.

[Table of Contents](#)**Results of Operations****Comparison of the Nine Months Ended September 30, 2020 and 2019**

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019:

(in thousands)	Nine Months Ended September 30,		
	2020	2019	Change
Operating expenses:			
Research and development	\$ 10,498	\$ 19,146	\$ (8,648)
General and administrative	9,364	8,504	860
Total operating expenses	19,862	27,650	(7,788)
Loss from operations	(19,862)	(27,650)	7,788
Other income (expense):			
Interest income	70	647	(577)
Interest expense	(730)	(944)	214
Change in fair value of derivative liability	(556)	(96)	(460)
Realized foreign exchange loss	1	(8)	9
Total other income (expense), net	(1,215)	(401)	(814)
Loss before income tax expense	(21,077)	(28,051)	6,974
Income tax expense	(32)	(81)	49
Net loss	<u>\$ (21,109)</u>	<u>\$ (28,132)</u>	<u>\$ 7,023</u>

Research and development expenses

Research and development expenses decreased by \$8.6 million from \$19.1 million for the nine months ended September 30, 2019 to \$10.5 million for the nine months ended September 30, 2020. The decrease was primarily attributable to a reduction in our research and development personnel and related expenses, and the completion of our preclinical efforts for our product candidate CTX-471 and the related filing of our IND in February 2019. We initiated efforts to reduce our research and development workforce in April 2019 which resulted in a decrease in salaries and related benefits of \$3.4 million. In addition, the transition of CTX-471 to the clinic and the completion of pre-clinical studies and filing of our IND resulted in research and development expenses decreasing additionally by \$4.7 million, of which \$1.5 million was due to a milestone payment we made under our collaboration agreement with Adimab LLC in 2019 while no such payments were made in 2020. Other research and development expenses decreased by \$0.5 million.

[Table of Contents](#)

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:

	Nine Months Ended	
	September 30,	
	2020	2019
CTX-471	\$ 2,250	\$ 4,733
CTX-8371	685	1
NKP30 cell engagement platform	22	709
Unallocated research and development expenses	7,541	13,703
Total research and development expenses	\$ 10,498	\$ 19,146

General and Administrative Expenses

General and administrative expenses increased by \$0.9 million from \$8.5 million for the nine months ended September 30, 2019 to \$9.4 million for the nine months ended September 30, 2020. The increase was primarily attributable to the issuance of stock options in August 2020 which resulted in an increase in stock compensation expense of \$2.1 million, as well as an increase in legal fees, professional fees, and facilities costs of \$0.5 million. These increases were partially offset by a reduction in headcount which resulted in a decrease in salaries and related benefits of \$1.7 million. 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 \$70,000 and \$0.6 million during the nine months ended September 30, 2020 and 2019, respectively. The decrease in interest income is primarily attributable to the lower interest rates on our cash and cash equivalents.

Interest expense

We recognized interest expense of \$0.7 million and \$0.9 million during the nine months ended September 30, 2020 and 2019, respectively. We began making principal payments in April 2020, reducing the average outstanding balance of our debt in the second quarter of 2020.

Change in fair value of derivative liability and success fee

We recognized a change in our derivative liability of \$0.6 million and \$0.1 million during the nine months ended September 30, 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 as required under our 2018 Credit Facility. The success fee was paid in June 2020 following the Merger.

Realized foreign exchange loss

Our realized foreign exchange losses were relatively small and unchanged during the nine months ended September 30, 2020 and 2019 as we have a limited number of payment arrangements denominated in a currency other than the U.S. dollar.

Income tax expense

During the nine months ended September 30, 2020 and 2019, we recognized income tax expenses of \$32,000 and \$81,000, respectively, and attributable to the services provided by the wholly-owned subsidiary of Compass Therapeutics LLC, prior to the closing of the Merger.

[Table of Contents](#)

Comparison of the Years Ended December 31, 2019 and 2018

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

(in thousands)	Year Ended December 31,		
	2019	2018	Change
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)	(37)
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	<u>\$ (34,744)</u>	<u>\$ (38,286)</u>	<u>\$ 3,542</u>

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,	
	2019	2018
	(in thousands)	
CTX-471	\$ 5,573	\$ 7,120
CTX 8371	29	—
NKP30 cell engagement platform	824	72
Unallocated research and development expenses	16,023	19,903
Total research and development expenses	<u>\$ 22,449</u>	<u>\$ 27,095</u>

[Table of Contents](#)

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 an expense 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 than 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

[Table of Contents](#)

operations primarily with proceeds from the sale of convertible preferred equity and borrowings under the 2018 Compass LLC Credit Facility. Through September 30, 2020, we had received gross proceeds of \$132.0 million from sales of Compass LLC equity securities and \$15.0 million in term loan borrowings under the Compass LLC credit facility and \$60.5 million in gross proceeds (\$53.6 in net proceeds) from the sale of our common stock in a private placement. As of September 30, 2020, we had cash and cash equivalents of \$55.5 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

[Table of Contents](#)

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:

(in thousands)	Year ended December 31,		Nine Months Ended September 30,	
	2019	2018	2020	2019
Cash used in operating activities	\$ (31,741)	\$ (33,679)	\$ (20,230)	\$ (26,150)
Cash (used in) provided by investing activities	(466)	(2,020)	32	(281)
Cash provided by financing activities	—	64,031	50,413	—
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ (32,207)	\$ 28,332	\$ 30,215	\$ (26,431)

Operating Activities

During the nine months ended September 30, 2020, we used \$20.2 million of cash in operating activities, resulting from our net loss of \$21.1 million and the change in operating assets and liabilities of \$4.0 million, offset by non-cash charges of \$4.9 million. Our non-cash charges were comprised of depreciation and amortization of \$1.3 million, sharebased compensation expense of \$3.0 million, non-cash interest expense of \$72,000, and a change in fair value of our derivative liability of \$0.6 million. The change in our operating assets was primarily related to the settlement of a derivative liability and a decrease in our accrued expenses due to the timing in which we pay our vendors.

During the nine months ended September 30, 2019, we used \$26.2 million of cash in operating activities, resulting from a net loss of \$28.1 million and a change in operating assets and liabilities of \$0.5 million, offset by non-cash charges of \$2.4 million. Non-cash charges were comprised of depreciation and amortization of \$1.6 million, share-based compensation expense of \$0.7 million, a change in fair value of our derivative liability of \$96,000 and non-cash interest expense of \$93,000. The change in our operating assets was primarily related to the net 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.

[Table of Contents](#)

Investing Activities

During the nine months ended September 30, 2020 provided by from investing activities was \$32,000 attributed to the sale of property and equipment for which we received \$55,000, offset by \$23,000 in purchases of property and equipment. During the nine months ended September 30, 2019, cash used in investing activities was \$0.3 million attributable to purchases of property and equipment.

During the years ended December 31, 2019 and 2018, cash used in investing activities was \$0.3 million, \$0.5 million and \$2.0 million, respectively, and attributable in each case to the purchases of property and equipment.

Financing Activities

We had no financing activities during the nine months ended September 30, 2019. During the nine months ended September 30, 2020 we received net cash proceeds of \$50.4 million from financing activities. This was primarily due to the closing of a private placement in June 2020, which resulted in net proceeds of \$54.2 million that were partially offset by \$3.8 in principal payments under the 2018 Credit Facility.

We had no financing activities 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 Compass LLC 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 Compass LLC 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 Compass LLC 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 April 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 1 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;

[Table of Contents](#)

- 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 September 30, 2020 will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2022, 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 initiate 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

[Table of Contents](#)

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:

(in thousands)	Payments due by Period				
	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.

[Table of Contents](#)

While our significant accounting policies are described in more detail in Note 3 to our consolidated financial statements, which are filed herein, 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 September 30, 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:

(in thousands)	Year Ended		Nine Months Ended	
	December 31,	2018	2020	2019
Research and development	\$383	\$284	\$ 486	\$278
General and administrative	532	372	2,480	411
Total unit-based compensation	<u>\$915</u>	<u>\$656</u>	<u>\$2,966</u>	<u>\$690</u>

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.

[Table of Contents](#)

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

[Table of Contents](#)

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 herein.

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 prospectus.

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.

Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

As of the Effective Time for the Merger, (i) Raich Ende Malter & Co. LLP, or REM, was dismissed as our independent registered public accounting firm, and (ii) our board of directors engaged CohnReznick LLP as the independent registered public accounting firm to audit the Company's financial statements for the fiscal year ending December 31, 2020.

REM's audit report to our financial statements for the fiscal years ended March 31, 2018 and 2019, respectively, did not contain an adverse opinion or a disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope or accounting principles.

During the fiscal years ended March 31, 2018 and 2019, respectively, and the subsequent interim period through the date of REM's dismissal, there were no disagreements with REM on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of REM, would have caused it to make reference to the subject matter thereof in connection with its report.

During the fiscal years ended March 31, 2018 and 2019 and the subsequent interim period through the date of REM's dismissal, neither the Company nor anyone acting on its behalf consulted CohnReznick LLP regarding the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements.

We have provided REM with a copy of this registration statement prior to the filing hereof and have requested that REM furnish to us a letter addressed to the SEC stating whether REM agrees with the statements made herein. REM has furnished such letter, which is filed as Exhibit 16.1 hereto, as required by Item 304(a)(3) of Regulation S-K.

DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

The following table sets forth the names and certain information regarding each of our directors and executive officers as of September 30, 2020:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
Executive Officers		
Thomas J. Schuetz, M.D., Ph.D.	59	Chief Executive Officer, President and Director
Vered Bisker-Leib, Ph.D., M.B.A.	50	President & Chief Operating Officer
Non-Employee Directors		
Phil Ferneau, M.B.A., J.D.(1)(2)	58	Director
Carl L. Gordon, Ph.D., CFA(2)	55	Director
Brett Kaplan, M.D.(1)	46	Director
Steven Squinto, Ph.D.(3)	64	Director
Julie Sunderland, M.B.A.(1)(3)	47	Director

- (1) Member of audit committee.
(2) Member of compensation committee.
(3) Member of nominating and corporate governance committee.

Executive Officers

Thomas J. Schuetz, M.D., Ph.D., has served as Compass's Chief Executive Officer since 2014. He has over 20 years of experience in oncology, biopharmaceutical drug development and life science venture investing. Dr. Schuetz co-founded Compass in 2014 following conceptual discussions while he was a venture partner at OrbiMed Advisors LLC. As a physician-scientist and serial entrepreneur, he aspired to create an antibody therapeutic company based on novel biology, protein engineering and key medical insights gathered throughout his career. While at OrbiMed, Dr. Schuetz co-founded Audentes Therapeutics, now a publicly traded biotechnology company where he remains a director. Also at OrbiMed, he participated in the investments in Enobia Pharma, Relypsa and Arteaus Therapeutics, and served as a director at each of those companies. Enobia was acquired by Alexion Pharmaceuticals in 2011, Relypsa was acquired by Galencia in 2016 and Arteaus was acquired by Eli Lilly in 2014. Dr. Schuetz has multiple years of clinical strategy, development and operations experience including roles as chief medical officer of Therion Biologics Corporation, a cancer vaccine company, and as the vice president of clinical affairs at Transkaryotic Therapies, a company acquired by Shire. Dr. Schuetz completed his medical training at Massachusetts General Hospital, where he served as the chief medical resident, and completed a medical oncology fellowship at the Dana-Farber Cancer Institute. Dr. Schuetz holds a B.S. in chemistry from Xavier University, an M.D. from Harvard Medical School and a Ph.D. in genetics from Harvard University. He is board certified in medical oncology. We believe that based on Dr. Schuetz's knowledge of our company, industry and business and his service as Compass's Chief Executive Officer, Dr. Schuetz is qualified to serve on our board of directors.

Vered Bisker-Leib, Ph.D., M.B.A., joined Compass in 2017 as its chief business officer and was promoted to President and Chief Operating Officer in 2020. In this role, she leads a team that spearheads finance, corporate development, strategy, operations, legal affairs and public and investor relations. Dr. Bisker-Leib is also a member of the board of directors of Ayala Pharmaceuticals. Prior to Compass, Dr. Bisker-Leib served as an executive-in-residence with Atlas Venture, where she provided business guidance to seed-stage companies. Previously, Dr. Bisker-Leib was the chief business officer of Cydan, a biotech accelerator, where she co-founded biotech companies focused on therapies addressing rare diseases. Before joining Cydan, Dr. Bisker-Leib was a member of Bristol-Myers Squibb's strategic transactions group where she assumed roles of increasing responsibility across five therapeutic areas, most recently as an executive director and global head of business development for the cardiovascular and metabolic franchises. Dr. Bisker-Leib earned her Ph.D. in chemical engineering and M.B.A. from University of Massachusetts, Amherst, where she was a Lois Pope M.B.A. Scholar. She has a B.Sc. in chemical engineering from the Israel Institute of Technology in Haifa.

Board Composition

Non-Employee Directors

Phil Ferneau, M.B.A., J.D., has served as a member of our board of directors since the closing of the Merger, and prior to that time served as a member of the board of directors of Compass OpCo since 2015. Mr. Ferneau is co-founder and Managing Partner of Borealis Ventures, a venture capital firm focused on healthcare opportunities. He currently leads Borealis' investments in Adimab, Amagma Therapeutics, Avitide, Compass OpCo, Evox Therapeutics, Orbit Discovery, Ovation.io, and Teckro. Mr. Ferneau was also responsible for the firm's prior investments in Avedro (IPO, then acquired by Glaukos: GKOS), GlycoFi (acquired by Merck & Co.), M2S (acquired by AIG Altaris Health Partners), and Vets First Choice (now Covetrus: CVET). Mr. Ferneau received an A.B. degree from Dartmouth College, a J.D. from the University of Virginia School of Law and an M.B.A. (with High Distinction) from the Tuck School of Business at Dartmouth. We believe that Mr. Ferneau is qualified to serve on our board of directors based on his extensive investment experience.

Carl L. Gordon, Ph.D., CFA, has served as a member of our board of directors since the closing of the Merger, and prior to that time served as a member of the board of directors of Compass OpCo since 2015. Dr. Gordon is a founding member, Managing Partner, and Co-Head of Global Private Equity at OrbiMed Advisors LLC, an investment firm. Dr. Gordon currently serves on the boards of directors of Keros Therapeutics Inc., ORIC Pharmaceuticals Inc., Turning Point Therapeutics, Inc., and Prevail Therapeutics, Inc., as well as several private companies. Dr. Gordon previously served on the boards of directors of several biopharmaceutical companies, including Alektor Inc., Arsanis, Inc. (which merged with X4 Pharmaceuticals, Inc.), Acceleron Pharma Inc., ARMO Biosciences, Inc., Intellia Therapeutics, Inc., Passage Bio Inc., Selecta Biosciences, Inc., and SpringWorks Therapeutics Inc. Dr. Gordon received a B.A. in Chemistry from Harvard College, a Ph.D. in Molecular Biology from the Massachusetts Institute of Technology, and was a Fellow at The Rockefeller University. We believe that Dr. Gordon is qualified to serve on our board of directors due to his scientific expertise, extensive business experience, and experience in venture capital and the life science industry.

Brett Kaplan, M.D., has served as a member of our board of directors since September 2020. Dr. Kaplan is the Chief Financial Officer of Prevail Therapeutics Inc, a clinical-stage gene therapy biotechnology company, focused on neurodegenerative disorders. Dr. Kaplan joined Prevail in 2018, which has raised \$175 million in equity financing, including the company's \$125 million IPO. From August 2010 to November 2018, Dr. Kaplan worked at Evercore, an investment bank, where he most recently served as Managing Director. At Evercore, he was involved in numerous strategic and financing transactions, including advising Bristol-Myers Squibb on its acquisitions of Celgene and Amylin and Takeda on its acquisitions of Shire and of Ariad, and the merger of Akebia and Keryx. Prior to Evercore, Dr. Kaplan was an Equity Research Analyst at Cowen and Company, an investment bank, from 2007 to 2010. Previously, Dr. Kaplan served as Director of Corporate Development at Cubist Pharmaceuticals, a pharmaceutical company acquired by Merck & Co., Inc. in 2014, Manager of Strategic Medical Marketing at Biopure Corporation, and Manager of Corporate Development and Strategy at Eli Lilly and Company. Dr. Kaplan received an M.B.B.Ch. and an M.B.A. from the University of Witwatersrand.

Steven Squinto, Ph.D., has served as a member of our board of directors since the closing of the Merger, and prior to that time served as a member of the board of directors of Compass OpCo since 2015. Dr. Squinto is an executive partner with OrbiMed Advisors LLC and has over twenty-five years of biotechnology industry experience. Dr. Squinto was a co-founder of Alexion Pharmaceuticals, Inc. and served as its executive vice president and chief global operations officer. Prior to 2013, he was Alexion's global head of research and development. From 1988 to 1992, Dr. Squinto held various positions at Regeneron Pharmaceuticals, Inc. Prior to Regeneron, he held a joint academic position at both the Tulane University and LSU Medical Schools. He is a recipient of numerous honors and awards from academic and professional organizations for his scientific work. Dr. Squinto currently serves on the board of directors of Springworks Therapeutics, Inc. and Passage Bio. Dr. Squinto previously served on the boards of directors of Arvinas, Inc. and Audentes Therapeutics, Inc. Dr. Squinto received his B.A. in chemistry and Ph.D. in biochemistry and biophysics from Loyola University of

[Table of Contents](#)

Chicago. We believe that Dr. Squinto is qualified to serve as a director based on his industry experience, including his operational experience in drug discovery and development, and service on multiple company boards.

Julie Sunderland, M.B.A., has served as a member of our board of directors since the closing of the Merger, and prior to that time served as a member of the board of directors of Compass OpCo since 2019. Ms. Sunderland is the co-founder of and a managing partner at Biomatics Capital Partners. Prior to founding Biomatics in 2016, Ms. Sunderland was director of program-related investments for the Bill & Melinda Gates Foundation. In that role, she led the foundation's \$1.5 billion strategic investment pool, funded 50 investments, including 30 in healthcare, and built a team of 10 investment professionals. Ms. Sunderland also chaired Bill & Melinda Gates Foundation's investment committee, which reviews all program-related investments. Prior to that role, she advised foundations, development finance institutions and governments on venture capital, SME financing and technical assistance programs. She also sits on the board of directors for several of Biomatics' portfolio companies including Aledade, BlackThorn, eGenesis and Verana Health. Ms. Sunderland holds a B.A. from Harvard University, an M.B.A. from Wharton Business School and an M.A. from Johns Hopkins School of Advanced International Studies. We believe that Ms. Sunderland is qualified to serve as a director based on her industry experience and service on multiple company boards.

Director Independence

Our board of directors has determined that all members of the board of directors except Thomas J. Schuetz are independent directors, including for purposes of the rules of the Nasdaq Stock Market and the federal securities laws and regulations. Thomas J. Schuetz is not an independent director under these rules because he is an executive officer of our company. In making such independence determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock. The composition and functioning of our board of directors and each of our committees will comply with applicable Nasdaq requirements and the rules and regulations of the SEC. There are no family relationships among any of our directors and executive officers.

Staggered Board of Directors

In accordance with the terms of our amended and restated certificate of incorporation, our board of directors will be divided into three staggered classes of directors as follows:

- Class I directors will be Julie Sunderland and Brett Kaplan;
- Class II directors will be Phil Ferneau and Carl L. Gordon; and
- Class III directors will be Thomas J. Schuetz and Steven Squinto.

At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2021 for Class I directors, 2022 for Class II directors and 2023 for Class III directors.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the number of directors will be fixed from time to time by a resolution of a majority vote of the directors then in office.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Role of Board in Risk Oversight Process

We have established a role of the chairperson of the board, who will be Carl L. Gordon, and we plan to keep this role separated from the role of Chief Executive Officer. We believe that separating these positions allows our Chief Executive Officer to focus on our day-to-day business, while the chairperson of the board will lead the board of directors in its fundamental role of providing advice to, and independent oversight of, management. Our board of directors recognizes the time, effort and energy that the Chief Executive Officer is required to devote to his position in the current business environment, as well as the commitment required to serve as chairperson of the board, particularly as the board of directors' oversight responsibilities continue to grow.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our financial condition, development and commercialization activities, operations, strategic direction and intellectual property, as more fully discussed in the section entitled "Risk Factors" appearing elsewhere in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing risk management is conducted primarily through the committees of the board of directors, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairperson of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Board Committees

As our common stock is not presently listed for trading or quotation on a national securities exchange, we are not presently required to have board committees. However, our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates pursuant to a charter adopted by our board of directors. The composition and functioning of all of our committees complies with all applicable requirements of the Sarbanes-Oxley Act and SEC rules and regulations, and we intend to comply with those of Nasdaq.

Audit Committee

Phil Ferneau, Brett Kaplan and Julie Sunderland serve on the audit committee, which is chaired by Brett Kaplan. Our board of directors has determined that Phil Ferneau, Brett Kaplan and Julie Sunderland are "independent" for audit committee purposes as that term is defined under SEC and Nasdaq Marketplace Rules, and each has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated Phil Ferneau and Brett Kaplan as "audit committee financial experts", as defined under the applicable rules of the SEC. The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;

Table of Contents

- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending, based upon the audit committee's review and discussions with management and our independent registered public accounting firm, whether our audited financial statements will be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and making recommendations to our board of directors regarding all such transactions; and
- reviewing earnings releases.

Compensation Committee

Phil Ferneau and Carl L. Gordon serve on the compensation committee, which is chaired by Carl L. Gordon. Our board of directors has determined that each member of the compensation committee is "independent" as defined under the Nasdaq Marketplace Rules. The compensation committee's responsibilities include:

- annually reviewing and approving the corporate goals and objectives to be considered in determining the compensation of our Chief Executive Officer;
- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and based on such evaluation: (i) recommending to the board of directors the cash compensation of our Chief Executive Officer and (ii) reviewing and recommending to the independent directors on the board of directors regarding grants and awards to our Chief Executive Officer under equity-based plans;
- reviewing and approving the cash compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the Nasdaq Marketplace Rules;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors;
- preparing the compensation committee report required by SEC rules, if and when required, to be included in our annual proxy statement; and
- reviewing and approving the retention, termination or compensation of any consulting firm or outside advisor to assist in the evaluation of compensation matters.

Nominating and Corporate Governance Committee

Steven Squinto and Julie Sunderland serve on the nominating and corporate governance committee, which is chaired by Steven Squinto. Our board of directors has determined that each member of the nominating and

[Table of Contents](#)

corporate governance committee is “independent” under the Nasdaq Marketplace Rules. The nominating and corporate governance committee’s responsibilities include:

Our board of directors may, from time to time, establish other committees.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Board Diversity

Our nominating and corporate governance committee is responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and for its individual members. In evaluating the suitability of individual candidates (both new candidates and current members), the nominating and corporate governance committee, in recommending candidates for election, and the board of directors, in approving (and, in the case of vacancies, appointing) such candidates, will take into account many factors, including the following:

- personal and professional integrity;
- ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly held company;
- experience in the industries in which we compete;
- experience as a director or executive officer of another publicly held company;
- diversity of expertise and experience in substantive matters pertaining to our business relative to other board members;
- conflicts of interest; and
- practical and mature business judgment.

Our board of directors evaluates each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. We intend to make available our code of business conduct and ethics on our website at <https://www.compasstherapeutics.com/>. We expect that any amendments to the code, or any waivers of its requirements, will be disclosed on our website. The reference to our web address does not constitute incorporation by reference of the information contained at, or available through, our website.

Limitation on Liability and Indemnification Matters

Our certificate of incorporation contains, and our amended and restated certificate of incorporation will contain, provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by

[Table of Contents](#)

Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law, or the DGCL; or
- any transaction from which the director derived an improper personal benefit.

Our certificate of incorporation and bylaws provide, and our amended and restated certificate of incorporation and amended and restated bylaws will provide, that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his, her or its actions in that capacity regardless of whether we would otherwise be permitted to indemnify him, her or it under Delaware law.

In addition to the indemnification required in our certificate of incorporation and bylaws (and, upon their effectiveness, our amended and restated certificate of incorporation and amended and restated bylaws), we have entered or intend to enter into indemnification agreements with each of our directors, officers and certain other employees. These agreements will provide for the indemnification of our directors, officers and certain other employees for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them by reason of the fact that they are or were our agents. We believe that these provisions in our certificate of incorporation, bylaws, amended and restated certificate of incorporation, amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. This description of the limitation of liability and indemnification provisions of our certificate of incorporation, bylaws, amended and restated certificate of incorporation, amended and restated bylaws and indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to this prospectus.

The limitation on liability and the indemnification provisions in our certificate of incorporation, bylaws, amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors, officers or employees as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director, officer or employee.

Involvement in Certain Legal Proceedings

None of our directors or executive officers has been involved in any of the following events during the past 10 years:

- any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;

Table of Contents

- any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offences);
- being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his or her involvement in any type of business, securities or banking activities; or
- being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated.

Non-Employee Director Compensation

Compass OpCo became our wholly-owned subsidiary upon the closing of the Merger on June 17, 2020. The following summarizes the compensation earned by the non-employee directors of Compass OpCo for the fiscal year ended December 31, 2019. Other than as set forth in the table below, we did not pay any compensation, make any additional equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors for the fiscal year ended December 31, 2019. Directors who also serve as employees received no additional compensation for their service as directors.

Director Compensation Table

<u>NAME</u>	<u>FEES EARNED OR PAID IN CASH(\$)</u>	<u>STOCK AWARDS(\$)(1)</u>	<u>TOTAL(\$)</u>
Steven Tregay.	50,000	—	50,000
Stephen Squinto	45,000	—	45,000
Carl Gordon	—	—	—
Phil Ferneau	—	—	—
Timothy Anderson	—	—	—
Benjamin Auspitz	—	—	—
Stephen Knight	—	—	—
Julie Sunderland	—	—	—
Errik Anderson	—	—	—

(1) As of December 31, 2019, Dr. Tregay and Dr. Squinto held 15,625 and 13,542 unvested incentive units, respectively.

During fiscal year 2019, Mr. Tregay received an annual cash retainer of \$50,000 and Dr. Squinto received an annual cash retainer of \$45,000. We also reimburse non-employee members of our board of directors for reasonable travel and out-of-pocket expenses incurred in attending meetings of our board of directors and committees of our board of directors. We intend to reevaluate our director compensation arrangements following the Merger.

EXECUTIVE COMPENSATION

Compass OpCo became our wholly-owned subsidiary upon the closing of the Merger on June 17, 2020, and its senior management became our senior management. The following summarizes the compensation earned by the executive officers of Compass OpCo named in “—*Summary Compensation Table*” below (referred to herein as our “named executive officers”) for the fiscal year ended December 31, 2019.

This section also discusses the material elements of the executive compensation policies and decisions of Compass OpCo and important factors relevant to an analysis of these policies and decisions. It provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our named executive officers and is intended to place in perspective the information presented in the following tables and the corresponding narrative. The following section is historical and has not been adjusted to give effect to the Merger or the related Share Conversion.

Overview

Historically, the executive compensation program of Compass OpCo has reflected its growth and corporate goals. To date, the compensation of the named executive officers has consisted of a combination of base salary, annual cash bonus, and long-term equity incentive compensation in the form of incentive units, and other employee benefits generally available to the company’s employees.

The named executive officers of Compass OpCo for the year ended December 31, 2019 were as follows:

- Thomas J. Schuetz, M.D., Ph.D., Chief Executive Officer;
- Vered Bisker-Leib, Ph.D., M.B.A., Chief Operating Officer; and
- Michael Schmidt, Ph.D., former Senior Vice President of Research.

Compensation Decisions

Compensation decisions are primarily made by the compensation committee. The compensation committee meets annually to discuss the progress of the company toward its strategic and business goals, and performance of the executive management of the company. In addition, the compensation committee determines and approves the compensation of the executive officers, including the named executive officers. The compensation committee also meets periodically on an ad hoc basis to address miscellaneous compensation matters.

Elements of Executive Compensation

Base Salaries. Base salaries for the named executive officers are determined annually by the board of directors or compensation committee, based on the scope of each officer’s responsibilities along with his or her respective experience and contributions during the prior year. When reviewing base salaries, the board of directors takes factors into account such as each officer’s experience and individual performance, the company’s performance as a whole, data from surveys of compensation paid by comparable companies, and general industry conditions, but does not assign any specific weighting to any factor.

Annual Cash Bonuses. Prior to the Merger, all of the named executive officers were eligible to receive annual discretionary cash bonuses from Compass OpCo and, following the Merger, all of the named executive officers will participate in the Compass Therapeutics, Inc. annual cash bonus program, which promotes and rewards the executives for the achievement of key strategic and business goals. For 2019, the compensation committee assessed the performance of each of the executive officers, and considered the promotion of the Chief Business Officer to Chief Operating Officer and of the Vice President of Research to Senior Vice President of Research. Accordingly, Dr. Bisker-Leib and Dr. Schmidt received discretionary cash bonuses based on performance in 2019 equal to \$160,876 and \$143,550, respectively. Dr. Schuetz elected to receive his bonus in additional equity.

[Table of Contents](#)

Equity Awards. The board of directors believes that equity grants provide executives with a strong link to the company's long-term performance, create an ownership culture and help to align the interests of executive officers and the company's equityholders. Accordingly, the compensation committee periodically reviews the equity incentive compensation of the named executive officers and from time to time may grant equity incentive awards to them. During fiscal year 2019, Compass OpCo granted an aggregate of 5,800,000 incentive units to Dr. Schuetz, 3,350,000 incentive units to Dr. Bisker-Leib, and 2,275,000 incentive units to Dr. Schmidt.

Other Benefits. The named executive officers are eligible for additional benefits, such as participation in our 401(k) plan, life insurance and health benefits that are generally available to all employees.

Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by or paid to each of the named executive officers for the periods ended December 31, 2019.

<u>NAME AND PRINCIPAL POSITION</u>	<u>YEAR</u>	<u>SALARY(\$)</u>	<u>BONUS(\$)</u>	<u>STOCK AWARDS(\$)(1)</u>	<u>TOTAL(\$)</u>
Thomas J. Schuetz, M.D., Ph.D. <i>Chief Executive Officer</i>	2019	400,000	—	973,843	1,373,843
Vered Bisker-Leib, Ph.D., M.B.A. <i>Chief Operating Officer</i>	2019	325,000	160,875	569,159	1,055,034
Michael Schmidt, Ph.D. <i>Former Senior VP of Research(2)</i>	2019	256,529	143,550	372,564	772,643

- (1) The amounts represent the fair value of the stock awards as of the grant date as computed in accordance with FASB ASC Topic 718, not including any estimates of forfeitures. The assumptions used in calculating the grant date fair value of the stock awards reported in the Stock Awards column are set forth in Note 9 to our financial statements for the year ended December 31, 2019. Note that the amounts reported in this column reflect the accounting cost for these stock awards, and do not correspond to the actual economic value that may be received by the named executive officers from the awards.

- (2) Dr. Schmidt resigned in February 2020.

[Table of Contents](#)

Outstanding Equity Awards at Fiscal Year-End 2019

The following table sets forth information concerning outstanding equity awards for each of the named executive officers as of December 31, 2019 and the numbers below have not been adjusted to give effect to the Merger and the related Share Conversion:

Name and Principal Position	Vesting Commencement Date(1)	Stock Awards			
		Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(2)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)(2)
Thomas J. Schuetz, M.D., Ph.D. <i>Chief Executive Officer</i>	2/22/2018	1,194,905	255,808	—	—
	7/3/2019(4)	2,508,333	436,304	—	—
	12/20/2019	3,000,000	501,755	—	—
Vered Bisker-Leib, Ph.D., M.B.A. <i>Chief Operating Officer</i>	12/1/2017	750,000	160,562	—	—
	—	—	—	750,000(5)	160,562
	7/3/2019(4)	1,209,375	210,361	—	—
	12/20/2019	2,000,000	334,504	—	—
Michael Schmidt, Ph.D. <i>Former Senior VP of Research(3)</i>	7/27/2015(6)	57,500	3,213	—	—
	9/1/2016	3,750	441	—	—
	3/1/2017	17,188	2,813	—	—
	2/22/2018	108,333	23,192	—	—
	7/3/2019(4)	1,321,354	229,839	—	—
	12/20/2019	800,000	133,801	—	—

- (1) Unless otherwise noted below, all stock awards are incentive units that follow a standard vesting schedule which provides for 25% of the total units vesting on the first anniversary of the vesting commencement date and the balance of the total units vesting in equal monthly installments on the last day of each of the next 36 one-month periods. All such stock awards are also subject to full acceleration in the event that the holder of such award is terminated without “cause” or resigns for “good reason” within one year of an “acquisition”, as such terms are defined in the applicable award agreement.
- (2) The amount represents the fair market value of the unvested or unearned incentive units as of December 31, 2019.
- (3) Dr. Schmidt resigned in February 2020. Upon his resignation, Dr. Schmidt forfeited 2,271,667 incentive units.
- (4) The total units vest in equal monthly installments following the vesting commencement date on the last day of each of the next 48 one-month periods.
- (5) In 2018, we granted 750,000 incentive units to Dr. Bisker-Leib, which vest as follows upon the achievement of a business milestone: 25% of the total units vesting on the first anniversary of the achievement of the business milestone and the balance of the total units vesting in equal monthly installments on the last day of each of the next 36 one-month periods.
- (6) 50% of the total units vested four years following the vesting commencement date and 50% vest six years following vesting commencement date.

Employment Arrangements with our Named Executive Officers

Thomas J. Schuetz, M.D., Ph.D.

Dr. Schuetz, our Chief Executive Officer and co-founder, has been employed by Compass OpCo since June of 2014. Dr. Schuetz does not have an employment agreement or an employment letter with Compass OpCo.

[Table of Contents](#)

Vered Bisker-Leib, Ph.D., M.B.A.

On November 8, 2017, Compass OpCo entered into an offer letter with Dr. Bisker-Leib for the position of Chief Business Officer. The offer letter provides for her at-will employment and sets forth her initial base salary and bonus target, initial equity award, and eligibility for the company's benefit plans generally. Effective January 1, 2020, Dr. Bisker-Leib was promoted to Chief Operating Officer pursuant to a promotion letter. In connection with her promotion, she received a salary increase and an additional equity award.

Michael Schmidt, Ph.D.

On July 2, 2015, Compass OpCo entered into an offer letter with Dr. Michael Schmidt for the position of Director of Protein Engineering. The offer letter provides for his at-will employment and sets forth his initial base salary and bonus target, initial equity award, and eligibility for the company's benefit plans generally. In May 2019, Dr. Schmidt was promoted to Senior Vice President of Research. Dr. Schmidt resigned from Compass OpCo in February 2020.

Employee Benefit Plans

2020 Stock Option and Incentive Plan

Our 2020 Stock Option and Incentive Plan, or 2020 Plan, was adopted by our board of directors and approved by our stockholders on June 17, 2020. The 2020 Plan will allow the compensation committee to make equity-based incentive awards to our officers, employees, directors and other key persons, including consultants.

Authorized Shares. We have initially reserved 2,930,836 shares of our common stock for the issuance of awards under the 2020 Plan, or the Initial Limit. The 2020 Plan provides that the number of shares reserved and available for issuance under the 2020 Plan will automatically increase each January 1, beginning on January 1, 2021, by the lesser of (i) 4% of the outstanding number of shares of our common stock on the immediately preceding December 31 or (ii) such number of shares as determined by the plan administrator no later than the immediately preceding December 31. This number will be subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. The shares we issue under the 2020 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated, other than by exercise, under the 2020 Plan will be added back to the shares of common stock available for issuance under the 2020 Plan. The maximum number of shares of common stock that may be issued as incentive stock options in any one calendar year period may not exceed the Initial Limit cumulatively increased on January 1, 2021 and on each January 1 thereafter by the lesser of 4% of the number of outstanding shares of common stock as of the immediately preceding December 31, or 2,930,836 shares.

Non-Employee Director Limit. Our 2020 Plan contains a limitation whereby the value of all awards under our 2020 Plan and all other cash compensation paid by us to any non-employee director may not exceed \$500,000.

Administration. The 2020 Plan will be administered by our compensation committee. Our compensation committee will have full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2020 Plan. The plan administrator is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants.

Eligibility. Persons eligible to participate in the 2020 Plan will be those employees, non-employee directors and consultants, as selected from time to time by our compensation committee in its discretion.

[Table of Contents](#)

Options. The 2020 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant unless the option is granted (i) pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of the Code or (ii) to individuals who are not subject to U.S. income tax. The term of each option will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Stock Appreciation Rights. Our compensation committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Restricted Stock and Restricted Stock Units. Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment or other service relationship with us through a specified vesting period.

Unrestricted Stock Awards. Our compensation committee may grant shares of common stock that are free from any restrictions under the 2020 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Dividend Equivalent Rights. Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

Cash-Based Awards. Our compensation committee may grant cash bonuses under the 2020 Plan to participants, subject to the achievement of certain performance goals.

Sale Event. The 2020 Plan provides that upon the effectiveness of a “sale event,” as defined in the 2020 Plan, an acquirer or successor entity may assume, continue or substitute for the outstanding awards under the 2020 Plan. To the extent that awards granted under the 2020 Plan are not assumed or continued or substituted by the successor entity, the 2020 Plan and all awards granted under the 2020 Plan shall terminate. In such case, except as may be otherwise provided in the relevant award agreement, all options and stock appreciation rights with time-based vesting, conditions or restrictions that are not exercisable immediately prior to the sale event will become fully exercisable as of the sale event, all other awards with time-based vesting, conditions or restrictions will become fully vested and nonforfeitable as of the sale event, and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in connection with the sale event in the plan administrator’s discretion or to the extent specified in the relevant award agreement. In the event of such termination, individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified time period, as determined by the compensation committee, prior to the sale event. In addition, in connection with the termination of the 2020 Plan upon a sale event, we may make or provide for a cash payment to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights; provided, that any options or stock appreciation rights with exercise prices equal to or greater than such per share cash consideration will be cancelled for no consideration. We may also make or provide for a

[Table of Contents](#)

payment, in cash or in kind, to the participants holding other awards in an amount equal to the per share cash consideration payable to stockholders in the sale event multiplied by the number of vested shares of common stock under such awards.

Amendment. Our board of directors may amend or discontinue the 2020 Plan and our compensation committee can amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely and materially affect rights under an award without the holder's consent. Certain amendments to the 2020 Plan or the terms of outstanding options or stock appreciation rights will require the approval of our stockholders.

No awards may be granted under the 2020 Plan after the date that is 10 years from the date on which the 2020 Plan became effective. No awards under the 2020 Plan have been made prior to the date hereof.

Senior Executive Cash Incentive Bonus Plan

On June 17, 2020, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan, which became effective following the Merger. The Bonus Plan is administered by our compensation committee. The Bonus Plan provides for cash bonus payments based upon the attainment of performance targets established by our compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to our company, or corporate performance goals, as well as individual performance objectives.

Our compensation committee may select corporate performance goals from among the following: developmental, publication, clinical or regulatory milestones and results; cash flow (including, but not limited to, operating cash flow and free cash flow); revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of our common stock; economic value-added; acquisitions, licenses or strategic transactions; financing or other capital raising transactions; operating income (loss); return on capital, assets, equity, or investment; stockholder returns; return on sales; total shareholder return; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of our common stock; bookings, new bookings or renewals; sales or market shares; number of prescriptions or prescribing physicians; coverage decisions; leadership development, employee retention, and recruiting and other human resources matters; operating income and/or net annual recurring revenue, any of which may be (i) measured in absolute terms or compared to any incremental increase, (ii) measured in terms of growth, (iii) compared to another company or companies or to results of a peer group, (iv) measured against the market as a whole and/or as compared to applicable market indices and/or (v) measured on a pre-tax or post-tax basis (if applicable).

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The corporate performance goals will be calculated in accordance with our financial statements, GAAP, or under a methodology established by our compensation committee at the beginning of the performance period and which is consistently applied with respect to a corporate performance goal in the relevant performance period. The compensation committee will measure the corporate performance goals after our financial reports for the applicable performance period have been published or such other appropriate time as the compensation committee determines. If the corporate performance goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period. Subject to the rights contained in any agreement between the executive officer and us, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment. The Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion and provides the compensation committee with discretion to adjust the size of the award as it deems appropriate.

Retirement Plan

We offer a 401(k) plan to eligible employees, including our named executive officers. In accordance with this plan, all eligible employees may contribute a percentage of compensation up to a maximum of the statutory limits per year. As of December 31, 2019, we did not make contributions to the plan. We implemented a 4% matching contribution as of January 1, 2020, as well as a discretionary match. We intend for the 401(k) plan to qualify, depending on the employee's election, under Section 401(a) of the Code, so that contributions by employees, and income earned on those contributions, are not taxable to employees until withdrawn from the 401(k) plan.

Indemnification of Officers and Directors

We have agreed to indemnify our directors and executive officers in certain circumstances. See "Directors, Executive Officers, Promoters and Control Persons—Limitation on Liability and Indemnification Matters".

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

SEC rules require us to disclose any transaction or currently proposed transaction in which we were a participant and in which any related person has or will have a direct or indirect material interest involving the lesser of \$120,000 or 1% of the average of our total assets as of the end of last two completed fiscal years, which are referred to as related party transactions. A related person is any executive officer, director, nominee for director or holder of 5% or more of our common stock, or an immediate family member of any of those persons. The descriptions set forth above under the captions “The Merger and Related Transactions—Merger Agreement”, “—the Private Placement”, “—Registration Rights”, “—2020 Stock Option and Incentive Plan”, “Executive Compensation—Employment and Related Agreements” and “Non-Employee Director Compensation” and below under “Description of Securities” are incorporated herein by reference.

The following is a description of related party transactions since January 1, 2017 in which any of our directors, executive officers or holders of more than 5% of the pre-Merger equity capital of Compass OpCo, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation and other arrangements that are described in the section titled “Executive Compensation”. The following description is historical and has not been adjusted to give effect to the Merger.

Sales and Purchases of Securities***Sales of Series A-4B Preferred Units***

In July 2017 and December 2017, Compass OpCo issued an aggregate of 22,216,583 Series A-4B preferred units to accredited investors at a price per unit of \$0.9834 for aggregate gross proceeds of approximately \$21.8 million. The table below sets forth the number of Series A-4B preferred units sold to our directors, executive officers or holders of more than 5% of the pre-Merger equity capital of Compass OpCo, or an affiliate or immediate family member thereof. Each Series A-4B preferred unit of Compass OpCo was converted into approximately 1.75 shares of our common stock in connection with the Merger.

Purchasers	Series A-4B Preferred Units	Aggregate Purchase Price
Thomas J. Schuetz	712,844	\$ 701,011
OrbiMed Private Investments V- KA LP	10,872,176	10,691,698
F-Prime Entities(1)	3,513,403	3,455,081
Cowen Healthcare Investments Entities(2)	4,067,520	3,999,999
Borealis Ventures Entities(3)	1,016,880	1,000,000

- (1) Consists of (i) 1,300,277 Series A-4B preferred units owned by F-Prime Capital Partners HC International Fund IV LP, and (ii) 2,213,126 Series A-4B preferred units owned by F-Prime Capital Partners HC Cambridge Fund IV LP. See footnote 3 to the beneficial ownership table in the section “Security Ownership of Certain Beneficial Owners and Management” for a description of the affiliation of the F-Prime entities.
- (2) Consists of 4,067,520 Series A-4B preferred units owned by CHI II Holdco LP. See footnote 4 to the beneficial ownership table in the section “Security Ownership of Certain Beneficial Owners and Management” for a description of the affiliation of the Cowen Healthcare Investments entities.
- (3) Consists of 1,016,880 Series A-4B preferred units owned by Vox Health Fund, L.P. See footnote 5 to the beneficial ownership table in the section “Security Ownership of Certain Beneficial Owners and Management” for a description of the affiliation of the Borealis Ventures entities.

Sales of Series A-5 Preferred Units

In June 2018, Compass OpCo issued an aggregate of 44,739,689 Series A-5 preferred units to accredited investors at a price per unit of \$1.10 for aggregate gross proceeds of approximately \$49.2 million. The table

Table of Contents

below sets forth the number of Series A-5 preferred units sold to our directors, executive officers or holders of more than 5% of the pre- Merger share capital of Compass OpCo, or an affiliate or immediate family member thereof. Each Series A-5 preferred unit of Compass OpCo was converted into approximately 0.85 shares of our common stock, in connection with the Merger.

<u>Purchasers</u>	<u>Series A-5 Preferred Units</u>	<u>Aggregate Purchase Price</u>
Thomas J. Schuetz	447,397	\$ 492,137
OrbiMed Private Investments V- KA LP	5,225,596	\$ 5,748,156
Anderson Entities(1)	3,149,674	\$ 3,464,641
F-Prime Entities(2)	1,776,165	\$ 1,953,781
Cowen Healthcare Investments Entities(3)	10,451,192	\$ 11,496,311
Borealis Ventures Entities(4)	1,046,909	\$ 1,151,600
Rivendell Investments 2016-6 LLC	10,451,192	\$ 11,496,311

- (1) Consists of (i) 724,783 Series A-5 preferred units owned by GTP AW Fund I LLC, (ii) 1,811,957 Series A-5 preferred units owned by GTP AW Fund II LLC, and (iii) 612,934 Series A-5 preferred units owned by Ulysses Consolidated LLC. See footnote 2 to the beneficial ownership table in the section “Security Ownership of Certain Beneficial Owners and Management” for a description of the affiliation of the Anderson entities.
- (2) Consists of (i) 657,673 Series A-5 preferred units owned by F-Prime Capital Partners HC International Fund IV LP, and (ii) 1,118,492 Series A-5 preferred units owned by F-Prime Capital Partners HC Cambridge Fund IV LP. See footnote 3 to the beneficial ownership table in the section “Security Ownership of Certain Beneficial Owners and Management” for a description of the affiliation of the F-Prime entities.
- (3) Consists of (i) 2,787,283 Series A-5 preferred units owned by Cowen Private Investments LP and (ii) 7,663,909 Series A-5 preferred units owned by CHI II Holdco LP. See footnote 4 to the beneficial ownership table in the section “Security Ownership of Certain Beneficial Owners and Management” for a description of the affiliation of the Cowen Healthcare Investments entities.
- (4) Consists of 1,046,909 Series A-5 preferred units owned by Borealis Granite Fund, L.P. See footnote 5 to the beneficial ownership table in the section “Security Ownership of Certain Beneficial Owners and Management” for a description of the affiliation of the Borealis Ventures entities.

Participation in the Private Placement

Certain of our existing institutional investors, including investors affiliated with certain of our directors, have purchased an aggregate of 7.1 million shares of our common stock in the Private Placement, for an aggregate gross purchase price of \$35.5 million. Such purchases were made on the same terms as the shares that were sold to other investors in the Private Placement and not pursuant to any pre-existing contractual rights or obligations.

Participation in this Offering

Certain of our principal stockholders, including stockholders affiliated with certain of our directors, have indicated an interest in purchasing a substantial amount of the shares of our common stock offered in this offering at the public offering price and on the same terms and conditions as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discounts and commissions on any shares purchased by these parties as they will on any other shares sold to the public in this offering.

Indemnification Agreements and Directors' and Officers' Liability Insurance

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses, such as attorneys' fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

Employment Agreements and Offer Letters

At the parent company level, we do not have employment agreements with Thomas J. Schuetz, our Chief Executive Officer, and Vered Bisker-Leib, our President and Chief Operating Officer.

On November 8, 2017, our subsidiary, Compass OpCo, entered into an offer letter with Dr. Bisker-Leib for the position of Chief Business Officer. The offer letter provides for her at-will employment and sets forth her initial base salary and bonus target, initial equity award, and eligibility for the company's benefit plans generally. Effective January 1, 2020, Dr. Bisker-Leib was promoted to Chief Operating Officer pursuant to a promotion letter. In connection with her promotion, she received a salary increase and an additional equity award. The offer letter and promotion letter remain in place with Compass OpCo, which became our wholly owned subsidiary following the Merger.

Compass OpCo does not have an offer letter with Dr. Schuetz.

Other Transactions

We have granted incentive units to our executive officers. For a description of these incentive units granted to such individuals, see the section titled "Executive Compensation". We have also granted incentive units to certain members of the board of directors. For a description of these incentive units, see the section titled "Non-Employee Director Compensation".

Policies and Procedures for Related-Person Transactions

Our board of directors has adopted a written related-person transaction policy, to be effective upon the consummation of the Merger, setting forth the policies and procedures for the review and approval or ratification of related-person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds \$120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's-length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

MARKET INFORMATION FOR OUR COMMON STOCK

No public market currently exists for our common stock. In connection with this offering, we have applied to list our common stock on The Nasdaq Capital Market under the symbol “CMPX”.

As of September 30, 2020, we had 52,120,062 shares of common stock outstanding held by 210 stockholders of record.

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 September 30, 2020 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 September 30, 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 52,120,062 shares of common stock outstanding as of September 30, 2020. Shares of common stock that a person has the right to acquire within 60 days of September 30, 2020, if any, 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.

Certain of our principal stockholders, including stockholders affiliated with certain of our directors, have indicated an interest in purchasing a substantial amount of the shares of our common stock offered in this offering at the public offering price and on the same terms and conditions as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discounts and commissions on any shares purchased by these parties as they will on any other shares sold to the public in this offering. The following table does not reflect any such potential purchases by these stockholders or their affiliated entities. If any shares are purchased by these stockholders, the number of shares of common stock beneficially owned after this offering and the percentage of common stock beneficially owned after this offering would increase from that set forth in the table below.

<u>Name of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned</u>	<u>Percentage of Shares beneficially Owned</u>
<i>Greater than 5% Stockholders:</i>		
OrbiMed Private Investments V-KA, LP(1)	12,714,404	24.4%
Anderson Entities(2)	5,290,270	10.2%
F-Prime Capital Partners Healthcare Fund IV LP(3)	4,122,414	7.9%
Cowen Healthcare Investments Entities(4)	3,181,684	6.1%
Consonance Entities(5)	3,000,000	5.8%
Borealis Ventures Entities(6)	2,749,256	5.3%

Table of Contents

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares beneficially Owned
Named Executive Officers and Directors:		
Thomas J. Schuetz, MD, Ph.D.(7)	4,525,467	8.7%
Vered Bisker-Leib, Ph.D., M.B.A.(8)	513,401	1.0%
Phil Ferneau, M.B.A., J.D.(5)	400,280	*
Carl L. Gordon, Ph.D., CFA(1)	12,714,404	24.4%
Brett Kaplan, M.D.	—	—
Steven Squinto, Ph.D.(1)(9)	34,540	*
Julie Sunderland, M.B.A.(10)	2,502,025	4.8%
All current directors and executive officers as a group (6 persons)	20,690,117	39.7%

* 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) 1,080,331 shares of common stock held of record by Ulysses Consolidated, LLC, (iii) 110,000 shares of common stock held of record by Ulysses Diversified Holdings LLC, (iv) 1,661,899 shares of common stock held of record by GTP AW Fund I, LLC, and (v) 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 (iii) and shared voting and investment power of the securities held by the entities described above in clauses (iv) and (v). 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 4,122,414 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 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, Massachusetts 02210.
- (4) Consists of (i) 590,159 shares of common stock held of record by Cowen Private Investments LP, or CPI, (ii) 2,416,797 shares of common stock held of record by Cowen Healthcare Investments II LP, or CHI II, and (iii) 174,728 shares of common stock held of record by CHI EF II LP, or CHI EF. CHI Advisors LLC, the investment adviser of CPI, CHI II and CHI EF has voting and investment power with respect to the shares held by each of CPI and CHI II. The address for CPI, CHI II and CHI EF 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

Table of Contents

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 Adviser and Mitchell Blutt, as the Manager & Member of Capman and Chief Executive Officer of the Capital Management Adviser and the Capital Opportunity Adviser, may be deemed to control Capman, the Capital Management Adviser and the Capital Opportunity Adviser. 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 Adviser, 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, New Hampshire 03755.
- (7) Includes 586,546 shares of restricted stock over which Dr. Schuetz has voting power.
- (8) Includes 410,530 shares of restricted stock over which Dr. Bisker-Leib has voting power.
- (9) Includes 916 shares of restricted stock over which Dr. Squinto has voting power.
- (10) Consists of 2,502,025 shares of common stock owned directly by Biomaterials Capital Partners, LP. Julie Sunderland, a member of our board of directors, is the co-founder of and a managing partner at Biomaterials Capital Partners, and exercises shared voting and investment power of the securities held by Biomaterials Capital Partners, LP. The address for Biomaterials Capital Partners, LP is 245 Main St., Cambridge, Massachusetts 02142.

DESCRIPTION OF CAPITAL STOCK

We have authorized capital stock consisting of 300,000,000 shares of common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share. Except as otherwise provided in the certificate of designation of any series of preferred stock we may issue, the number of authorized shares of common stock or preferred stock may from time to time be increased or decreased (but not below the number of shares of such class outstanding) by the affirmative vote of the holders of a majority in voting power of the outstanding shares of our capital stock.

As of the date of this prospectus, we had 52,120,062 shares of common stock issued and outstanding, and no shares of preferred stock issued and outstanding. Unless stated otherwise, the following discussion summarizes the term and provisions of our amended and restated certificate of incorporation and our amended and restated bylaws.

Common Stock

The holders of outstanding shares of common stock are entitled to receive dividends out of assets or funds legally available for the payment of dividends at such times and in such amounts as the board of directors from time to time may determine. Holders of common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. There is no cumulative voting of the election of directors then standing for election. The common stock is not entitled to pre-emptive rights and is not subject to conversion or redemption. Upon liquidation, dissolution or winding up of our company, the assets legally available for distribution to stockholders are distributable ratably among the holders of the common stock after payment of liquidation preferences, if any, on any outstanding payment of other claims of creditors. Each outstanding share of common stock is duly and validly issued, fully paid and non-assessable.

Preferred Stock

Shares of preferred stock may be issued from time to time in one or more series, each of which will have such distinctive designation or title as may be determined by our board of directors prior to the issuance of any shares thereof. Preferred stock will have such voting powers, full or limited, or no voting powers, and such preferences and relative, participating, optional or other special rights and such qualifications, limitations or restrictions thereof, as shall be stated in such resolution or resolutions providing for the issue of such class or series of preferred stock as may be adopted from time to time by the board of directors prior to the issuance of any shares thereof.

While we do not currently have any plans for the issuance of additional preferred stock, the issuance of such preferred stock could adversely affect the rights of the holders of common stock and, therefore, reduce the value of the common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of the common stock until the board of directors determines the specific rights of the holders of the preferred stock; however, these effects may include:

- Restricting dividends on the common stock;
- Diluting the voting power of the common stock;
- Impairing the liquidation rights of the common stock; or
- Delaying or preventing a change in control of our company without further action by the stockholders.

Other than in connection with shares of preferred stock, which preferred stock is not currently designated nor contemplated by us, and the division of our board of directors into three classes with staggered three-year terms, we do not believe that any provision of our amended and restated certificate of incorporation or amended and restated bylaws would delay, defer or prevent a change in control.

Other Convertible Securities

As of the date hereof, other than the securities described above, we do not have any outstanding convertible securities.

Anti-Takeover Effects of Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware Law

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: (i) acquisition of us by means of a tender offer (ii) acquisition of us by means of a proxy contest or otherwise, or (iii) removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the price of our common stock.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the DGCL, which prohibits a person deemed an “interested stockholder” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date such person becomes an interested stockholder unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the price of our common stock.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Special Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by a majority of our board of directors then in office.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation will eliminate the right of stockholders to act by written consent without a meeting.

Classified Board; Election and Removal of Directors

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of our common stock outstanding will be able to elect all of our directors. In addition, our directors may not be removed without cause, and removal of our directors for cause will require a supermajority (66 2/3%) stockholder vote. For more information on the classified board of directors, see the section titled “Management—Board Composition”. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Choice of Forum

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any state law claims for: (i) any derivative action or proceeding brought on behalf of our company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to the company or our stockholders, (iii) any action asserting a claim against our company arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws, (iv) any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation or bylaws, or (v) any action asserting a claim against our company governed by the internal affairs doctrine. This exclusive forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Unless we consent in writing to the selection of an alternate forum, the United States District Court for the District of Massachusetts is the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, as our principal executive office is located Cambridge, Massachusetts. Although our amended and restated bylaws contain the choice of forum provision described above, it is possible that a court could rule that such provisions are inapplicable for a particular claim or action or that such provisions are unenforceable.

Amendment of Charter and Bylaw Provisions

The amendment of any of the above provisions in our amended and restated certificate of incorporation and amended and restated bylaws, except for the provision making it possible for our board of directors to issue convertible preferred stock, would require a supermajority (66 2/3% and majority of the minority, if applicable) stockholder vote.

The provisions of the DGCL, our amended and restated certificate of incorporation and amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Limitations of Liability and Indemnification Matters

For a discussion of liability and indemnification, see the section titled “Directors, Executive Officers, Promoters and Control Persons—Limitation on Liability and Indemnification Matters”.

Transfer Agent

We have appointed American Stock Transfer & Trust Company to serve as transfer agent and registrar for our common stock.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to the Merger, there has been a limited public market for our common stock. In connection with this offering, we have applied to list our common stock on The Nasdaq Capital Market under the symbol “CMPX”. We cannot predict the effect, if any, that future sales of shares of common stock, or the availability for future sale of shares of common stock, will have on the market price of shares of our common stock prevailing from time to time. The sale of substantial amounts of shares of our common stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of shares of our common stock.

Based on the number of shares outstanding as of September 30, 2020, upon completion of this offering, we will have a total of 61,120,062 shares of common stock outstanding (or 62,470,062 shares of common stock if the underwriters exercise in full their option to purchase additional shares of common stock). Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares, including shares sold to an entity affiliated with an existing shareholder that may purchase shares in this offering, held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below.

Lock-up Agreements

In connection with this offering, we, along with our directors, executive officers and certain stockholders have agreed with the underwriters that for a period of 180 days (the restricted period), after the date of this prospectus, subject to specified exceptions, we or they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock.

Certain of our employees, including our executive officers and/or directors, may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

Rule 144

Pursuant to Rule 144 promulgated under the Securities Act, sales of the securities of a former shell company, such as us, under that rule are not permitted (i) until at least 12 months have elapsed from June 23, 2020, the filing date of our Current Report on Form 8-K, reflecting our status as a non-shell company, and (ii) unless at the time of a proposed sale, we are subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act and have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Exchange Act, as applicable, during the preceding 12 months, other than Current Reports on Form 8-K. We are currently a “voluntary filer” and are not subject to the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. As a result, unless we register shares subject to Rule 144 for sale under the Securities Act, our stockholders will be forced to hold their shares of common stock for at least that 12-month period before they are eligible to sell those shares, and even after that 12-month period, sales may not be made under Rule 144 unless we and any selling stockholders are in compliance with other requirements of Rule 144.

In general, Rule 144 provides that (i) any of our non-affiliates that has held restricted common stock for at least 12 months is thereafter entitled to sell its restricted stock freely and without restriction, provided that we remain compliant and current with our SEC reporting obligations, and (ii) any of our affiliates, which includes our directors, executive officers and other person in control of us, that has held restricted common stock for at least 12 months is thereafter entitled to sell its restricted stock subject to the following restrictions: (a) we are compliant and current with our SEC reporting obligations, (b) certain manner of sale provisions are satisfied,

[Table of Contents](#)

(c) a Form 144 is filed with the SEC, and (d) certain volume limitations are satisfied, which limit the sale of shares within any three-month period to a number of shares that does not exceed 1% of the total number of outstanding shares or, if our common stock is then listed or quoted for trading on a national securities exchange, then the greater of 1% of the total number of outstanding shares and the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of the Form 144 with respect to the sale. A person who has ceased to be an affiliate at least three months immediately preceding the sale and who has owned such shares of common stock for at least one year is entitled to sell the shares under Rule 144 without regard to any of the limitations described above.

Regulation S

Regulation S under the Securities Act provides that shares owned by any person may be sold without registration in the U.S., provided that the sale is effected in an offshore transaction and no directed selling efforts are made in the U.S. (as these terms are defined in Regulation S), subject to certain other conditions. In general, this means that our shares of common stock may be sold in some other manner outside the United States without requiring registration in the United States.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement, in compliance with Rule 701 under the Securities Act, before the effective date of the Merger (to the extent such common stock is not subject to a lock-up agreement) is entitled to rely on Rule 701 to resell such shares beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act in reliance on Rule 144, but without compliance with the holding period requirements contained in Rule 144. Accordingly, subject to any applicable lock-up agreements, beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act, under Rule 701 persons who are not our “affiliates,” as defined in Rule 144, may resell those shares without complying with the minimum holding period or public information requirements of Rule 144, and persons who are our “affiliates” may resell those shares without compliance with Rule 144’s minimum holding period requirements (subject to the terms of the lock-up agreements described above, if applicable).

Stock Plans

We intend to file with the SEC a registration statement under the Securities Act covering the shares of common stock that are outstanding or reserved for issuance under the 2020 Plan. Such registration statement is expected to be filed and become effective as soon as practicable after the consummation of the Merger and the registration of our shares of common stock with the SEC pursuant to this Registration Statement on Form S-1. Accordingly, shares registered under such registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

UNDERWRITING

Citigroup Global Markets Inc., Credit Suisse Securities (USA) LLC and Stifel, Nicolaus & Company, Incorporated are acting as joint book-running managers of the offering and as representatives of the underwriters named below. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, each underwriter named below has severally agreed to purchase, and we have agreed to sell to that underwriter, the number of shares set forth opposite the underwriter's name.

<u>Underwriter</u>	<u>Number of Shares</u>
Citigroup Global Markets Inc.	
Credit Suisse Securities (USA) LLC	
Stifel, Nicolaus & Company, Incorporated	
Raymond James & Associates, Inc.	
Total	9,000,000

The underwriting agreement provides that the obligations of the underwriters to purchase the shares included in this offering are subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all the shares (other than those covered by the underwriters' option to purchase additional shares described below) if they purchase any of the shares.

Shares sold by the underwriters to the public will initially be offered at the public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount from the public offering price not to exceed \$ _____ per share. If all the shares are not sold at the initial offering price, the underwriters may change the offering price and the other selling terms.

If the underwriters sell more shares than the total number set forth in the table above, we have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 1,350,000 additional shares at the public offering price less the underwriting discount. To the extent the option is exercised, each underwriter must purchase a number of additional shares approximately proportionate to that underwriter's initial purchase commitment. Any shares issued or sold under the option will be issued and sold on the same terms and conditions as the other shares that are the subject of this offering.

Certain of our principal stockholders, including stockholders affiliated with certain of our directors, have indicated an interest in purchasing a substantial amount of the shares of our common stock offered in this offering at the public offering price and on the same terms and conditions as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discounts and commissions on any shares purchased by these parties as they will on any other shares sold to the public in this offering.

We, our officers and directors, and certain other stockholders have agreed that, for a period of 180 days from the date of this prospectus, we and they will not, without the prior written consent of Citigroup, Credit Suisse and Stifel, dispose of or hedge any shares or any securities convertible into or exchangeable for our common stock. Citigroup, Credit Suisse and Stifel in their sole discretion may release any of the securities subject to these lock-up agreements at any time without notice.

We have applied to list our common stock on The Nasdaq Capital Market under the symbol "CMPX".

Table of Contents

The following table shows the underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters' over-allotment option.

	Paid by Us	
	No Exercise	Full Exercise
Per share	\$	\$
Total	\$	\$

In connection with the offering, the underwriters may purchase and sell shares in the open market. Purchases and sales in the open market may include short sales, purchases to cover short positions, which may include purchases pursuant to the underwriters' option to purchase additional shares, and stabilizing purchases.

- Short sales involve secondary market sales by the underwriters of a greater number of shares than they are required to purchase in the offering.
 - "Covered" short sales are sales of shares in an amount up to the number of shares represented by the underwriters' option to purchase additional shares.
 - "Naked" short sales are sales of shares in an amount in excess of the number of shares represented by the underwriters' option to purchase additional shares.
- Covering transactions involve purchases of shares either pursuant to the underwriters' option to purchase additional shares or in the open market in order to cover short positions.
 - To close a naked short position, the underwriters must purchase shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
 - To close a covered short position, the underwriters must purchase shares in the open market or must exercise the option to purchase additional shares. In determining the source of shares to close the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the underwriters' option to purchase additional shares.
- Stabilizing transactions involve bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum.

Purchases to cover short positions and stabilizing purchases, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the shares. They may also cause the price of the shares to be higher than the price that would otherwise exist in the open market in the absence of these transactions. The underwriters may conduct these transactions on the Nasdaq Capital Market, in the over-the-counter market or otherwise. If the underwriters commence any of these transactions, they may discontinue them at any time.

Conflicts of Interest

The underwriters are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. The underwriters and their respective affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial

[Table of Contents](#)

instruments (which may include bank loans and/or credit default swaps) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

Notice to Prospective Investors in the European Economic Area

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a relevant member state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of shares described in this prospectus may not be made to the public in that relevant member state other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the relevant member state has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the relevant Dealer or Dealers nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For purposes of this provision, the expression an “offer of securities to the public” in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe for the shares, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, and the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the relevant member state) and includes any relevant implementing measure in the relevant member state. The expression 2010 PD Amending Directive means Directive 2010/73/EU.

The sellers of the shares have not authorized and do not authorize the making of any offer of shares through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the shares as contemplated in this prospectus. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of the shares on behalf of the sellers or the underwriters.

Notice to Prospective Investors in the United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the “Order”) or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (each such person being referred to as a

[Table of Contents](#)

“relevant person”). This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Prospective Investors in France

Neither this prospectus nor any other offering material relating to the shares described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers*. The shares have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the shares has been or will be:

- released, issued, distributed or caused to be released, issued or distributed to the public in France; or
- used in connection with any offer for subscription or sale of the shares to the public in France.

Such offers, sales and distributions will be made in France only:

- to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d'investisseurs*), in each case investing for their own account, all as defined in, and in accordance with articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French *Code monétaire et financier*;
- to investment services providers authorized to engage in portfolio management on behalf of third parties; or
- in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French *Code monétaire et financier* and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des Marchés Financiers*, does not constitute a public offer (*appel public à l'épargne*).

The shares may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French *Code monétaire et financier*.

Notice to Prospective Investors in Hong Kong

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

Notice to Prospective Investors in Japan

The shares offered in this prospectus have not been and will not be registered under the Financial Instruments and Exchange Law of Japan. The shares have not been offered or sold and will not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan (including any corporation or

[Table of Contents](#)

other entity organized under the laws of Japan), except (i) pursuant to an exemption from the registration requirements of the Financial Instruments and Exchange Law and (ii) in compliance with any other applicable requirements of Japanese law.

Notice to Prospective Investors in Singapore

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

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

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

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

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

Notice to Prospective Investors in the State of Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728 - 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728 - 1968, including, inter alia, if: (1) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions, or the Addressed Investors; or (2) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 - 1968, subject to certain conditions, or Qualified Investors. The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. We have not and will not take any action that would require us to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 - 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

[Table of Contents](#)

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728 - 1968. In particular, we may request that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (1) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968; (2) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968 regarding Qualified Investors is applicable to it; (3) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 -1968 and the regulations promulgated thereunder in connection with this offering; (4) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 -1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 -1968; and (5) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Certain legal matters in connection with this offering will be passed upon for the underwriters by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York.

EXPERTS

The financial statements of Compass OpCo as of, and for each of the years, in the two-year period ended December 31, 2019 and 2018, have been included herein and in the registration statement in reliance upon the report of CohnReznick LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC this registration statement on Form S-1 under the Securities Act with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes a part of this registration statement, does not contain all of the information in this registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, you should refer to this registration statement and the exhibits filed as part of this document. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to this registration statement. Each of these statements is qualified in all respects by this reference.

We are subject to the informational requirements of the Exchange Act and file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including this registration statement, over the Internet on the SEC's website at <http://www.sec.gov>. You may also request a copy of these filings, at no cost, by writing or telephoning us at: 245 First Street, 3rd Floor, Cambridge, Massachusetts 02142, (847) 673-1700.

**COMPASS THERAPEUTICS LLC AND SUBSIDIARY
CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018**

[Table of Contents](#)

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
INDEX
December 31, 2019 and 2018

	<u>Page(s)</u>
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Financial Statements	
Consolidated Balance Sheets	F-2
Consolidated Statements of Operations	F-3
Consolidated Statements of Preferred Units and Members' Deficit	F-4
Consolidated Statements of Cash Flows	F-5
Notes to Consolidated Financial Statements	F-6 – F-27

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

**The Board of Directors and Members
Compass Therapeutics LLC**

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Compass Therapeutics LLC and Subsidiary (the “Company”) as of December 31, 2019 and 2018, and the related consolidated statements of operations, preferred units and members’ deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ CohnReznick LLP

We have served as the Company’s auditor since March 2020.

Roseland, New Jersey

June 23, 2020

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
(In thousands, except units and unit data)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,303	\$ 57,511
Prepaid expenses and other current assets	935	1,370
Total current assets	26,238	58,881
Property and equipment, net	3,751	5,367
Restricted cash	263	262
Other assets	129	115
Total assets	<u>\$ 30,381</u>	<u>\$ 64,625</u>
Liabilities, Convertible Preferred Units and Members' Deficit		
Current liabilities:		
Current portion of long-term debt	\$ 5,576	\$ 3,688
Accounts payable	629	1,730
Accrued expenses	3,122	2,657
Derivative liability related to loan	494	390
Total current liabilities	9,821	8,465
Long-term debt, including accretion, net of current portion	9,293	11,064
Total liabilities	19,114	19,529
Commitments (Note 11)		
Convertible preferred units (Series A-1, A-2, A-3, A-4, A4B and A-5) 207,164,404 units authorized, issued, and outstanding as of December 31, 2019 and 2018; aggregate liquidation preference \$132,039,394 as of December 31, 2019 and 2018	129,870	129,870
Members' deficit:		
Class A common units—305,346,089 units authorized at December 31, 2019 and 2018; 75,632,932 and 66,578,491 units issued and outstanding at December 31, 2019 and 2018, respectively	2,585	1,670
Class C common units—4,509,750 units authorized, issued, and outstanding at December 31, 2019 and 2018	720	720
Accumulated deficit	(121,908)	(87,164)
Total members' deficit	(118,603)	(84,774)
Total liabilities, convertible preferred units and members' deficit	<u>\$ 30,381</u>	<u>\$ 64,625</u>

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

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands,)

	Year Ended	
	December 31,	
	2019	2018
Operating expenses:		
Research and development	\$ 22,449	\$ 27,095
General and administrative	11,603	11,217
Total operating expenses	<u>34,052</u>	<u>38,312</u>
Loss from operations	(34,052)	(38,312)
Other income (expense):		
Interest income	743	663
Interest expense	(1,228)	(767)
Change in fair value of call right liability	—	313
Change in fair value of derivative liability	(104)	(67)
Realized foreign exchange loss	(12)	(13)
Total other income (expense), net	<u>(601)</u>	<u>129</u>
Loss before income taxes	(34,653)	(38,183)
Income taxes	(91)	(103)
Net loss	<u>\$ (34,744)</u>	<u>\$ (38,286)</u>

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

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF PREFERRED UNITS AND MEMBERS' DEFICIT
YEARS ENDED DECEMBER 31, 2019 AND 2018
(In thousands, except units)

	Preferred Units		Common Units		Common Units		Common Units		Accumulated Deficit	Total Members' Deficit
	Series A-1, A-2, A-3, A-4A, A4B and A-5		Class A		Class B		Class C			
	Units	Amount	Units	Amount	Units	Amount	Units	Amount		
Balances at December 31, 2017	<u>162,424,715</u>	<u>\$ 81,513</u>	<u>5,078,488</u>	<u>\$ 181</u>	<u>46,542,838</u>	<u>\$ 833</u>	<u>—</u>	<u>\$ —</u>	<u>\$ (48,878)</u>	<u>\$ (47,864)</u>
Additional issuance costs in connection with the prior issuance of Series A4B preferred units	—	(7)	—	—	—	—	—	—	—	—
Issuance of Series A-5 preferred units—net of issuance costs of \$129,241	44,739,689	49,084	—	—	—	—	—	—	—	—
Issuance of Class C common units associated with Series A-5 preferred units	—	(720)	—	—	—	—	4,509,750	720	—	720
Redesignation of Class B common units	—	—	46,542,838	833	(46,542,838)	(833)	—	—	—	—
Issuance of profit interests and related unit compensation expense	—	—	16,143,382	656	—	—	—	—	—	656
Forfeiture of common units	—	—	(1,186,217)	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(38,286)	(38,286)
Balances at December 31, 2018	<u>207,164,404</u>	<u>\$ 129,870</u>	<u>66,578,491</u>	<u>\$ 1,670</u>	<u>—</u>	<u>\$ —</u>	<u>4,509,750</u>	<u>\$ 720</u>	<u>\$ (87,164)</u>	<u>\$ (84,774)</u>
Issuance of profit interests and related unit compensation expense	—	—	19,643,100	915	—	—	—	—	—	915
Forfeiture of common units	—	—	(10,588,659)	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(34,744)	(34,744)
Balances at December 31, 2019	<u>207,164,404</u>	<u>\$ 129,870</u>	<u>75,632,932</u>	<u>\$ 2,585</u>	<u>—</u>	<u>\$ —</u>	<u>4,509,750</u>	<u>\$ 720</u>	<u>\$ (121,908)</u>	<u>\$ (118,603)</u>

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

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended	
	December 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (34,744)	\$ (38,286)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,120	1,921
Loss/(gain) on disposal of fixed asset	5	(15)
Non-cash interest expense	116	121
Unit-based compensation	915	656
Change in fair value of derivative liability related to loan	104	67
Change in fair value of call right liability	—	(313)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	435	112
Other long term assets	(56)	69
Accounts payable	(1,101)	992
Accrued expenses	509	999
Deferred rent	(44)	(2)
Net cash used in operating activities	<u>(31,741)</u>	<u>(33,679)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(466)	(2,020)
Net cash used in investing activities	<u>(466)</u>	<u>(2,020)</u>
Cash flows from financing activities:		
Additional issuance costs from prior issuance of Series A4B preferred units	—	(7)
Proceeds from issuance of Series A-5 preferred units	—	49,213
Issuance costs from Series A-5 preferred units	—	(129)
Proceeds from borrowings under loan	—	15,000
Fees related to borrowings under loan	—	(46)
Net cash provided by financing activities	<u>—</u>	<u>64,031</u>
Net change in cash, cash equivalents and restricted cash	(32,207)	28,332
Cash, cash equivalents and restricted cash at beginning of year	57,773	29,441
Cash, cash equivalents and restricted cash at end of year	<u>\$ 25,566</u>	<u>\$ 57,773</u>
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ 1,115	\$ 556
Supplemental disclosure of noncash investing and financing activities		
Acquisition of equipment included in accrued expenses	\$ 3	\$ 105
Issuance of Class C common units associated with Series A-5 preferred units	\$ —	\$ 720

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

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

1. Nature of Business

Compass Therapeutics LLC, a limited liability company, was formed under the laws of the State of Delaware in January 2014. Compass Therapeutics LLC has a wholly owned subsidiary, Compass Therapeutics Advisors Inc., formed in February 2015. Compass Therapeutics LLC and its wholly-owned subsidiary (the “Company”) are headquartered in Massachusetts. The Company is a fully integrated drug discovery and development company focused on comprehensively drugging the immune system with combinations of human monoclonal antibodies, multiclons and engineered protein constructs.

The Company is subject to risks and uncertainties common to companies in the biotechnology and pharmaceutical industries. There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s technology will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

2. Liquidity, Uncertainties and Going Concern

In accordance with Accounting Standards Update (“ASU”) No. 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

Since its inception, the Company has funded its operations primarily with proceeds from the sale of preferred units and borrowings under loan agreements. The Company has incurred recurring losses since its inception, including net losses of \$34.7 million and \$38.3 million for the years ended December 31, 2019 and 2018, respectively. In addition, as of December 31, 2019, the Company had an accumulated deficit of \$121.9 million. The Company expects to continue to generate operating losses for the foreseeable future. As of the issuance date of the annual consolidated financial statements for the year ended December 31, 2019, the Company expected that its cash and cash equivalents after taking into consideration private offering that was completed in June 2020 (See Note 16) would be sufficient to fund its operating expenses and capital expenditure requirements into Q4 2021. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements are presented in U.S. dollars and have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and as amended by Accounting Standards Updates of the Financial Accounting Standards Board (“FASB”).

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Compass Therapeutics LLC and its wholly-owned subsidiary, Compass Therapeutics Advisors Inc. All intercompany accounts and transactions have been eliminated in consolidation.

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual of research and development expenses, the valuation of the preferred equity call right liability, the valuation of the embedded derivative, the valuation of common units and estimates associated with unit-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from those estimates. Changes in estimates are recorded in the period that they become known.

Segment Information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company has one operating segment. The Company's chief operating decision maker, its chief executive officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources. All of the Company's long-lived assets are held in the United States.

Cash and Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash with original maturities of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held in money market funds. Cash equivalents are stated at cost, which approximates market value. Cash equivalents consisted of money market funds of \$22.8 million and \$55.3 million at December 31, 2019 and 2018, respectively.

Restricted Cash

As of December 31, 2019 and 2018, the Company was required to maintain a separate cash balance of \$0.2 million to collateralize corporate credit cards with a bank, which was classified as restricted cash on the consolidated balance sheets as a non-current asset.

In connection with the Company's lease agreement entered into July 2016 (see Note 11), the Company is required to maintain a letter of credit of \$0.1 million for the benefit of the landlord. As of December 31, 2019, and 2018, the underlying cash balance securing this letter of credit was classified as restricted cash on the consolidated balance sheets as a non-current asset.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and restricted cash. The Company maintains its cash, cash equivalents, and restricted cash with financial institutions that management believes to be of high-credit quality. The Company generally maintains balances in various operating accounts at financial institutions that management believes to be of high-credit quality, in amounts that may exceed federally insured limits. The Company has not experienced any losses related to its cash, cash equivalents and restricted cash.

As of December 31, 2019 and 2018, the Company had no off-balance sheet risks such as foreign exchange contracts, option contracts or other hedging arrangements.

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization are recorded using the straight-line method over the estimated useful lives of the related assets as follows:

	Estimated Useful Life
Asset classification	
Equipment	5 years
Furniture and fixtures	7 years
Software	5 years
Leasehold improvements	Lesser of estimated useful life or lease term

Estimated useful lives are periodically assessed to determine if changes are appropriate. Maintenance and repairs are expensed as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation or amortization are eliminated from the consolidated balance sheet and any resulting gains or losses are included in the consolidated statement of operations in the period of disposal. Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service. Assets held under capital leases are stated at the lesser of the present value of future minimum lease payments or the fair value of the leased asset at the inception of the lease. Amortization of assets held under capital leases is computed using the straight-line method over the shorter of the estimated useful life of the asset or the period of the related lease.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. The Company did not record any impairment losses on long-lived assets during the years ended December 31, 2019 or 2018.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets and liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

An entity may choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings.

The Company's cash equivalents are carried at fair value according to the fair value hierarchy described above and were determined based on Level 1 measurements (see Note 4). The Company's restricted cash is carried at fair value according to the fair value hierarchy described above and were determined based on Level 2 measurements (see Note 4). The carrying values of other current assets and accounts payable approximate their fair value due to the short-term nature of these assets and liabilities. The carrying values of the Company's loan approximated its fair value as of December 31, 2019 and March 31, 2020 due to its variable interest rate. The fair value of the loan related embedded derivative (see Note 4) was determined based on Level 3 measurements.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in members' deficit as a reduction of proceeds generated as a result of the offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations. As of December 31, 2019 and 2018, the Company had no deferred offering costs.

Research and Development Costs

Costs associated with internal research and development and external research and development services, including drug development and preclinical studies, are expensed as incurred. Research and development expenses include costs for salaries, employee benefits, subcontractors, facility-related expenses, depreciation and amortization, unit-based compensation, third-party license fees, laboratory supplies, and external costs of outside vendors engaged to conduct discovery, preclinical and clinical development activities and clinical trials as well as to manufacture clinical trial materials, and other costs. The Company recognizes external research and development costs based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its service providers.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such prepaid expenses are recognized as an expense when the goods have been delivered or the related services have been performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

Costs associated with licenses of technology acquired as part of collaborative arrangements are expensed as incurred and are generally included in research and development expense in the consolidated statements of operations if it is determined the license has no alternative future use.

Accrued Research and Development Expenses

The Company has entered into various research and development and other agreements with commercial firms, researchers, universities and others for provisions of goods and services. These agreements are generally cancelable, and the related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Debt Issuance Costs

Debt issuance costs consist of payments made to secure commitments under certain debt financing arrangements. These amounts are recognized as interest expense over the period of the financing arrangement using the effective interest method. If the financing arrangement is canceled or forfeited, or if the utility of the arrangement to the Company is otherwise compromised, these costs are recognized as interest expense immediately.

The Company's consolidated financial statements present debt issuance costs related to a recognized debt liability as a direct reduction from the carrying amount of that debt liability.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expense in the consolidated statements of operations.

Unit-Based Compensation

The Company accounts for all unit-based awards granted to employees and non-employees as unit-based compensation expense at fair value. The Company measures the estimated fair value of the unit-based award on the date of grant.

The Company determines the fair value of the underlying profit interest units based on input from management and approved by the Board, which utilizes the Company's enterprise value determined utilizing various methods including the back-solve method, the option-pricing method ("OPM") or a hybrid of the probability-weighted expected return method ("PWERM") and the OPM. The total enterprise value is then allocated to the various outstanding equity instruments, including the underlying profit interest, utilizing the option-pricing model.

For employee and non-employee awards, the Company recognizes compensation expense over the requisite service period, which is generally the vesting period of the respective award based on the grant date fair value of the award. The Company accounts for forfeitures as they occur.

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

The fair value of each profits interest unit is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected unit price volatility, the expected term of the unit, the risk-free interest rate for a period that approximates the expected term of the units and the Company's expected dividend yield. The fair value of each restricted equity award is estimated on the date of grant based on the fair value of the Company's common units on that same date. As there is no public market for its common units, the Company determines the volatility for awards granted based on an analysis of reported data for a group of guideline companies that issued options with substantially similar terms. The expected volatility has been determined using a weighted-average of the historical volatility measures of this group of guideline companies. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded unit price. The expected term of the Company's units granted to employees has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The Company has elected to apply the nonpublic entity practical expedient for calculating the expected term of non-employee awards, using the midpoint between the vesting date and the contractual term, which is consistent with the method used for employee awards. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common units; therefore, the expected dividend yield is assumed to be zero.

Income Taxes

Compass Therapeutics LLC elected to be treated as a partnership for income tax reporting purposes and therefore, federal and Massachusetts and any other state income taxes are the responsibility of the individual members. As such, no federal or state income taxes related to the LLC are recorded in the consolidated financial statements. The Company's wholly-owned subsidiary, 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 the consolidated financial statements.

The Company follows the liability method of accounting for income taxes, as set forth in ASC 740, "*Accounting for Income Taxes*." ASC 740 provides for the recognition of deferred tax liabilities and assets for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. The guidance requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax asset to a level which, more likely than not, will be realized. See Note 15 "Income Taxes" for further discussion of income taxes.

ASC 740-10, "*Accounting for Uncertainty in Income Taxes*" ("ASC 740-10"), provides detailed guidance for financial statement recognition, measurement, and disclosure of uncertain tax positions recognized in an enterprise's financial statements. In accordance with ASC 740-10, income tax positions must meet a more likely than not recognition threshold at the effective date to be recognized upon the adoption of the standard and in subsequent periods. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits within operations as income tax expense over the next twelve months. The Company has no liabilities for uncertain tax positions recorded as of December 31, 2019 and 2018.

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

Net Loss per Unit

The Company follows the two-class method when computing net loss per unit as the Company has issued units that meet the definition of participating securities. The two-class method determines net income (loss) per unit for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common unitholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per unit attributable to common unitholders is computed by dividing the net income (loss) attributable to common unitholders by the weighted average number of common units outstanding for the period. Diluted net income (loss) attributable to common unitholders is computed by adjusting net income (loss) attributable to common unitholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per unit attributable to common unitholders is computed by dividing the diluted net income (loss) attributable to common unitholders by the weighted average number of common units outstanding for the period, including potential dilutive common units. For purpose of this calculation, outstanding profit interest options, convertible preferred unit and warrants to purchase shares of convertible preferred units are considered potential dilutive common units.

The Company's convertible preferred unit contractually entitles the holders of such units to participate in dividends but does not contractually require the holders of such units to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common unitholders, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common unitholders, diluted net loss per unit attributable to common unitholders is the same as basic net loss per unit attributable to common unitholders, since dilutive common units are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common unitholders for the years ended December 31, 2019 and 2018.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes existing revenue recognition guidance under GAAP. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle and will require companies to use more judgment and make more estimates than under the prior guidance. The Company expects that these judgments and estimates will include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. The Company adopted ASU 2014-09 as of January 1, 2018, and the adoption had no impact on the Company's consolidated financial statements as the Company does not currently have any revenue-generating arrangements.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). ASU 2016-09 identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. The

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

Company adopted ASU 2016-09 as of January 1, 2018, and the adoption did not have a material impact on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The Company adopted ASU 2017-09 as of January 1, 2018, and the adoption did not have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU No. 2018-07"). These amendments expand the scope of Topic 718, Compensation—Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The ASU supersedes Subtopic 505-50, Equity—Equity-Based Payments to Non-Employees. The Company adopted ASU 2018-07 as of January 1, 2018, and the adoption did not have a material impact on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230), Restricted Cash* ("ASU 2016-18"). ASU 2016-09 will require consistency for the presentation of restricted cash on the statement of cash flows. The new guidance requires amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted ASU 2016-18 as of January 1, 2018, and the adoption did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which requires a lessee to record a right-of-use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the consolidated financial statements as its date of initial application. If an entity chooses the second option, the transition requirements for existing leases also apply to leases entered into between the date of initial application and the effective date. The standard is effective for the Company beginning January 1, 2021, with early adoption permitted. The Company plans to adopt this standard on January 1, 2021 and is currently evaluating the expected impact that the standard could have on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurements*, which changes the fair value measurement disclosure requirements of ASC Topic 820. The goal of the ASU is to improve the effectiveness of ASC Topic 820's disclosure requirements. The standard is effective for the Company beginning January 1, 2020. The adoption of this guidance is not expected to be material to the Company's consolidated financial statements and related disclosures.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* ("ASU 2018-18"). The amendments in this update clarify that

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

certain transactions between collaborative arrangement participants should be accounted for as revenue when the collaborative arrangement participant is a customer in the context of a unit of account and precludes recognizing as revenue consideration received from a collaborative arrangement participant if the participant is not a customer. The standard is effective for the Company beginning January 1, 2021. The Company is currently evaluating the potential impact ASU 2018-18 may have on its financial position and results of operations upon adoption.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (“ASU 2019-12”), which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The new standard will be effective beginning January 1, 2022. The Company does not expect the adoption of ASU 2019-12 to have a material impact on the Company’s consolidated financial statements.

4. Fair Value Measurements

The following tables present information about the Company’s financial assets and liabilities that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurements as of December 31, 2019 Using:			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value at December 31,
Assets				
Cash equivalents—money market funds	\$ 22,784	\$ —	\$ —	\$ 22,784
Restricted cash	—	263	—	263
Total assets	<u>\$ 22,784</u>	<u>\$ 263</u>	<u>\$ —</u>	<u>\$ 23,047</u>
Liabilities				
Derivative liability related to loan	\$ —	\$ —	\$ 494	\$ 494
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 494</u>	<u>\$ 494</u>

	Fair Value Measurements as of December 31, 2018 Using:			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value at December 31,
Assets				
Cash equivalents—money market funds	\$ 55,291	\$ —	\$ —	\$ 55,291
Restricted cash	—	262	—	262
Total assets	<u>\$ 55,291</u>	<u>\$ 262</u>	<u>\$ —</u>	<u>\$ 55,553</u>
Liabilities				
Long term call right liability	\$ —	\$ —	\$ 390	\$ 390
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 390</u>	<u>\$ 390</u>

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

Valuation of Call Right Liability

As of December 31, 2017, the call right liability was comprised of the fair value of each investors' right to purchase their allotted A-5 preferred units at the predetermined purchase price as described in Note 8. These call rights were financial instruments that might create a conditional obligation to repurchase units for cash in the contract and were therefore recorded as liabilities and measured at fair value. The call right liability was settled in June 2018 with the issuance of Series A-5 preferred units ("Series A-5") as further described in Note 8 and is, therefore, no longer outstanding. The fair value of the Series A-5 call rights was based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The Company utilized a Monte Carlo model to value these instruments. The assumptions used, in the Monte Carlo Simulations to value the equity on a daily basis through the expected date of the A-4 close were as follows: expected term of 0.75 years, expected volatility of 64.2%, risk-free rate of return of 0.53%, current total unit value of \$67.5 million. An option pricing model was used to value the call right utilizing the following assumptions: equity price determined by Monte Carlo Simulations, expected term of 2.04 to 3.04 years, expected volatility of 67.4% to 68.7%, risk-free rate of return of 0.75% to 0.87%, and no expected dividend yield.

The following table provides a rollforward of the cumulative fair values of the Company's call right liability for which fair value is determined by Level 3 inputs (in thousands):

Balances at December 31, 2017	\$ 313
Decrease in fair value of call right liability at issuance of Series A-5	(313)
Balances at December 31, 2018	<u>\$ —</u>

Valuation of Derivative Liability

As of December 31, 2018, the Company's derivative liability was comprised of the contingent interest rate reset features and a contingent feature to pay a success fee upon the occurrence of certain liquidity events in accordance with the loan and security agreement (refer to Note 7). The Company classified these instruments as a liability on its consolidated balance sheets because these features were not clearly and closely related to its host instrument and met the definition of a derivative. The derivative liability was initially recorded at fair value upon issuance of the loan and is being subsequently remeasured to fair value at each reporting date. Changes in the fair value of the derivative liability are recognized as a component of other income (expense), net in the consolidated statements of operations.

The fair value of the derivative liability recognized in connection with the Company's loan and security agreement entered into on March 30, 2018 ("2018 Loan Agreement") (see Note 7) was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the derivative liability was determined using the probability-weighted expected return method, which considered as inputs the type, timing and probability of occurrence of a change-of-control event, the future equity financing and cash settlement of the loans; the potential amount of the payment under each of these potential settlement scenarios; and the risk-adjusted discount rate reflecting the expected risk profile for each of the potential settlement scenarios.

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

The following table provides a roll forward of the aggregate fair values of the Company's derivative liability, for which fair value is determined using Level 3 inputs (in thousands):

Balances at December 31, 2017	\$ —
Initial fair value of derivative liability in connection with loan	323
Change in fair value	67
Balances at December 31, 2018	390
Change in fair value	104
Balances at December 31, 2019	\$ 494

5. Property and Equipment

Property and equipment as of December 31, 2019 and 2018, consisted of the following (in thousands):

	<u>2019</u>	<u>2018</u>
Equipment	\$ 7,230	\$ 6,904
Furniture and fixtures	629	599
Leasehold Improvements	896	1,172
Software	669	581
Assets not yet placed in service	230	207
Total property and equipment—at cost	9,654	9,463
Less: Accumulated depreciation and amortization	(5,903)	(4,096)
Property and equipment, net	<u>\$ 3,751</u>	<u>\$ 5,367</u>

Total depreciation and amortization expense for the years ended December 31, 2019 and 2018, was \$2.1 and \$1.9, respectively.

6. Accrued Expenses

Accrued expenses as of December 31, 2019 and 2019 consisted of the following (in thousands):

	<u>2019</u>	<u>2018</u>
Accrued employee compensation and benefits	\$ 1,759	\$ 1,196
Accrued external research and development expenses	249	401
Accrued legal fees	417	279
Accrued interest expense	87	91
Accrued federal and state taxes	1	44
Accrued sales taxes	554	475
Other accrued expenses	55	171
Total accrued expenses	<u>\$ 3,122</u>	<u>\$ 2,657</u>

7. Loan Payable

On March 30, 2018, the Company entered into the 2018 Loan Agreement with Pacific Western Bank, Inc. ("PWB"), which provides for a term loan of up to \$15.0 million on the closing date, maturing and requiring full

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

repayment of principal and interest by March 1, 2022 (“Maturity Date”). The Company borrowed the full \$15.0 million available under the 2018 Loan Agreement in two separate tranches: \$10.0 million upon execution of the 2018 Loan Agreement in March 2018 (“Tranche I”), and \$5.0 million in September 2018 (“Tranche II”).

Borrowings under the 2018 Loan Agreement bear interest at a rate per year equal to the greater of 6.25% and 2.00% plus the Wall Street Journal prime rate; provided, however, that in the event the Company achieves certain milestones, the interest rate applicable to the borrowings under the 2018 Loan Agreement would be the greater of 6.25% and 1.50% plus the Wall Street Journal prime rate. In an event of default, as defined in the 2018 Loan Agreement, the interest rate applicable to borrowings would be increased by 5.0%.

The Company is required to make monthly payments of interest only, beginning on April 1, 2018 and continuing through March 30, 2019 (the “Interest Only End Date”), at which time the Company would begin making payments on the principal from April 1, 2019 through the Maturity Date. However, upon the achievement of certain milestones, the Interest Only End Date would be extended through September 30, 2019 or March 30, 2020, and the Maturity Date would be extended to September 1, 2022. The 2018 Loan Agreement allows for prepayment in full of the outstanding principal at any time, subject to a prepayment charge that is dependent on the prepayment date.

Per the 2018 Loan Agreement, upon a Liquidity Event, defined below, the Company would pay a success fee of \$0.8 million, or \$1.1 million if both Tranche I and Tranche II were issued (“Success Fee”). A Liquidity Event is defined as (a) any sale, license, or other disposition of all or substantially all of the assets of the Company, (b) any reorganization, consolidation, merger or sale of the voting securities of the Company or any other transaction where the holders of a Company’s securities before the transaction beneficially own less than 50% of the outstanding voting securities of the surviving entity after the transaction, or (c) an initial public offering of a Company’s equity securities.

Borrowings under the 2018 Loan Agreement are collateralized by substantially all of the Company’s personal property, excluding intellectual property. Under the 2018 Loan Agreement, the Company agreed to affirmative and negative covenants to which it would remain subject until maturity or repayment in full. The negative covenants included restrictions on the Company’s ability to incur additional indebtedness, pay dividends, encumber its property, or engage in certain fundamental business transactions, such as mergers or acquisitions of other businesses. The obligations under the 2018 Loan Agreement are subject to acceleration upon occurrence of specified events of default, including payment default, insolvency and a material adverse change in the Company’s business, operations or financial or other condition.

On September 26, 2018, the Company entered into the First Amendment to the 2018 Loan Agreement (the “First Amendment”) which amended the primary depository covenant by waiving violations on maintaining excess cash and decreasing the primary depository covenant. The First Amendment also amended the Success Fee due upon the occurrence of a Liquidity Event, from \$0.8 million with a contingent \$0.3 million upon the advance of the Tranche II, to the full \$1.1 million upon the occurrence of a Liquidity Event.

In March 2019, the Company entered into the Second Amendment to the 2018 Loan Agreement (the “Second Amendment”), which extended the second milestone date from March 31, 2019 to April 30, 2019. The first milestone was achieved in February 2018 which extended the interest only period through September 30, 2019.

In October 2019, the Company entered into the Third Amendment to the 2018 Loan Agreement (the “Third Amendment”), which extended the Interest Only End Date to March 31, 2020. The amendment also added an

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

additional covenant requiring the Company to maintain a minimum cash balance of \$6.0 million at PWB commencing April 2, 2020 if additional finance proceeds of \$40.0 million are not raised prior to April 2, 2020.

Each of the three amendments to the 2018 Loan Agreement were analyzed and determined to be debt modifications and not extinguishments.

The aggregate principal amount of debt outstanding as of December 31, 2019 and 2018 was \$15.0 million, including Tranche I and Tranche II amounts. Current and non-current debt obligations reflected in the consolidated balance sheets as of December 31, 2019 and 2018 consisted of the following (in thousands):

	December 31, 2018
Current liabilities:	
Term loan under the 2018 Loan Agreement	\$ 3,750
Unamortized debt discount	(62)
Loans payable, net of discount	3,688
Non-current liabilities:	
Term loan under 2018 Loan Agreement	11,250
Unamortized debt discount	(186)
Loans payable, net of discount and current portion	11,064
Total loans payable, net of discount	\$ 14,752

	December 31, 2019
Current liabilities:	
Term loan under the 2018 Loan Agreement	\$ 5,625
Unamortized debt discount	(49)
Loans payable, net of discount	5,576
Non-current liabilities:	
Term loan under 2018 Loan Agreement	9,375
Unamortized debt discount	(82)
Loans payable, net of discount and current portion	9,293
Total loans payable, net of discount	\$ 14,869

The Company recognized interest expense under the 2018 Loan Agreement, as amended, of \$1.2 million and \$0.8 million during the years ended December 31, 2019 and 2018, respectively, including interest expense related to the amortization of the debt discount of \$0.1 million and \$0.1 million, respectively. As of December 31, 2019 and 2018, the unamortized debt discount was \$0.1 million and \$0.2 million, respectively.

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

As of December 31, 2019, the aggregate minimum future principal payments due in connection with the 2018 Loan Agreement, as amended, are summarized as follows (in thousands):

<u>Year Ending December 31, 2020</u>	
2020	\$ 5,625
2021	7,500
2022	1,875
	<u>\$ 15,000</u>

8. Preferred Units and Associated Call Right Liability

As of December 31, 2019 and 2018, the preferred units consisted of the following:

<u>Preferred Units</u>	<u>Preferred Units Issued and Outstanding</u>	<u>Liquidation Preference (in thousands)</u>
Series A-1	64,704,832	\$ 15,978
Series A-2	36,782,734	15,000
Series A-3	23,467,151	15,000
Series A-4	15,253,415	15,000
Series A4B	22,216,583	21,848
Series A-5	44,739,689	49,214
	<u>207,164,404</u>	<u>\$ 132,040</u>

The rights, preferences, and privileges of the preferred units are as follows:

Voting Rights

The preferred unitholders are entitled to the number of votes equal to the number of Class A common units into which each preferred unit is convertible. Any action to be taken by the unit holders requires the affirmative vote of a majority of unitholders, unless a different vote is required, including without limitation, actions requiring consent of the requisite preferred holders.

Conversion

Each preferred unit is convertible, at the option of the holder, at any time, and without the payment of additional consideration, into Class A common units as is determined by dividing the original purchase price by the conversion price with respect to such preferred unit in effect at the time of conversion. The Series A-1 conversion price is \$0.2885 per unit, the Series A-2 conversion price is \$0.4078 per unit, the Series A-3 conversion price is \$0.6392, the Series A-4 and Series A4B conversion price is \$0.9834 and the Series A-5 conversion price is \$1.10.

**COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018**

Distribution

The Board shall, in its discretion, determine the timing and amount of any distribution to be made by the Company, in accordance with the operating agreement. Upon a liquidation event, proceeds are to be distributed in accordance with the following order of priority:

First, 100% to the members holding outstanding Series A-5, if any, to the extent of and in proportion to the Series A-5 units at \$1.10 a unit with respect to the outstanding Series A-5 units held by each such member;

Second, 100% to the members holding outstanding Series A4B, if any, to the extent of and in proportion to the Series A4B units at \$0.9834 a unit with respect to the outstanding Series A4B units held by each such member;

Third, 100% to the members holding outstanding Series A-4, if any, to the extent of and in proportion to the Series A-4 units at \$0.9834 a unit with respect to the outstanding Series A-4 units held by each such member;

Fourth, 100% to the members holding outstanding Series A-3, if any, to the extent of and in proportion to the Series A-3 units at \$0.6392 a unit with respect to the outstanding Series A-3 units held by each such member;

Fifth, 100% to the members holding outstanding Series A-2, if any, to the extent of and in proportion to the Series A-2 units at \$0.4078 a unit with respect to the outstanding Series A 2 units held by each such member; and

Sixth, 100% to the members holding outstanding Series A-1, if any, to the extent of and in proportion to the Series A-1 units at \$0.2885 a unit with respect to the outstanding Series A-1 units held by each such member; and

Seventh, after payment in full to the holders of outstanding preferred units of the full amounts distributable to them, 100% to the members holding outstanding common units, in proportion to the respective number of outstanding common units held by each member (in addition to any payments made in respect of profit interest units to the extent the distributions made to holders of other units exceed the applicable "strike price" of the incentive units in question).

Preferred units shall be automatically deemed and treated as if they were converted into common units solely for purposes of determining the distributions made pursuant to the order of priority above, if the common unit distribution amount equals or exceeds (A) the original issue price then applicable to such Series of preferred units plus (B) the per unit amount of any unpaid tax distributions, divided by (C) the number of common units then issuable upon conversion hereunder of one (1) unit of such series of preferred units.

Liquidation

In the event of any liquidation or deemed liquidation, dissolution or winding-up of the Company, the assets of the Company would be distributed in accordance with the same order of priority as distributions.

The holders of preferred units have liquidation rights in the event of a deemed liquidation that, in certain situations, are not solely within the control of the Company. Therefore, the preferred units are classified outside of members' deficit on the consolidated balance sheets.

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

Call Right Liability

In connection with a financing in 2015, the Series A-1 investors obtained call rights to purchase an aggregate of 36,782,737 units of Series A-2 at \$0.4078 per unit, 23,466,834 units of Series A-3 at \$0.6392 per unit, and 15,253,203 units of Series A-4 at \$0.9834 per unit upon reaching certain predetermined scientific milestones. As each milestone was met, each investor was able to purchase their allotted preferred units at the prices per unit described above. In the event an investor elected not to purchase their preferred units upon a milestone event, that investor's preferred units from the immediately preceding preferred unit round were automatically converted into Class A common units on a ten for one basis.

The call rights represented a freestanding financial instrument and required bifurcation from the preferred units. The call right is liability classified and was recorded upon issuance at fair value as a call right liability in the consolidated balance sheet. Subsequent changes in the fair value were recognized in the consolidated statement of operations in "change in fair value of call right liability" in the financial years that such changes related to. As of December 31, 2018, the call right liability had been settled as all issuances of Series A had been made.

Sale of Series A-5

In June 2018, the Company issued 44,739,689 units of Series A-5 at \$1.10 per unit and 4,509,750 units of Class C common units, for gross proceeds of \$ 49.2 million. Proceeds, net of issuance costs of \$0.1 million, were \$48.4 million. The Class C common units are intended to constitute "profits interests" for tax purposes and was valued at \$0.7 million using an option pricing model valuation approach. Refer to Note 9 for the discussion on the valuation methodology.

The Series A-5 call rights previously issued in connection with the 2015 financing were valued at \$0.3 million as of December 31, 2017. The valuation was based on the right having strike price of \$1.66 per unit of Series A-5. In June 2018, the call right was amended to \$1.10 per unit as the then Series A-5 fair value was \$1.10 per unit. The fair value of the call right liability was \$0 immediately before the Series A-5 financing. The Company recorded a gain in the consolidated statement of operations with a corresponding decrease to call right liability of \$0.3 million for the year ended December 31, 2018.

9. Common Units, Warrants and Unit Incentive Plans

Upon formation of the Company, a capital account was established for each member. The capital account of each member is adjusted for the cash and property contributed by or distributed to each member, the amount of net profits or loss allocated to the member, and other adjustments. Net profit or loss is allocated to the members in proportion to their respective member interests in the Company.

In connection with prior financing transactions the Company issued warrants to purchase common units. A summary of the outstanding warrants at both December 31, 2019 and March 31, 2020 is as follows:

<u>Date Granted</u>	<u>Number</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
6/17/2015	5,267,959	\$ 2.8474	7/17/2022
12/7/2015	5,267,959	\$ 2.8474	7/17/2022
9/7/2016	5,268,035	\$ 2.8474	7/17/2022
7/11/2017	5,268,034	\$ 2.8474	7/17/2022

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

The Company established two classes of its common units, one designated as Class A common units, each of which entitled its holder to one vote per unit; and the second designated as Class B common units, each of which entitled its holder to one vote per unit. In June 2018, the Board authorized the issuance of Class C common units and the Company redesignated Class B common units as Class A common units. As of December 31, 2018, Class A and Class C common units were the only classes of common units, each of which entitled its holder to one vote per unit. Due to employee terminations and resignations, 10,588,659 and 1,186,127 of Class A common units were forfeited during the years ended December 31, 2019 and 2018, respectively. The Company's outstanding common units have been issued from the incentive pool and the founders pool. In June 2018, the founders pool was dissolved. Certain incentive units available for issuance under the founder's pool were distributed to the holders of the Series A-3 and the Series A-4, as Class C common units. The remainder of the units available for issuance were redesignated as units available for issuance under the incentive pool as Class A common units. Common units in the incentive pool may be issued by the Board to employees, directors of, and consultants or advisors to the Company.

The Class C common units, issued to Series A-3, Series A-4 and Series A-5 holders, as well as the Class A common units issued or issuable under the incentive pool include incentive units (as defined in the restated operating agreement), are intended to constitute "profits interests" for tax purposes. Profits interest units are recorded as issued and outstanding common units when granted. Standard vesting for profits interests provide for 25% of units to vest after one year with the remaining vesting monthly thereafter over 36 months. As approved by the Board, some grants may have different vesting provisions. Class C common units were vested in full upon grant.

Unvested profits interests unit's activity for the year ended December 31, 2019 and 2018, was as follows:

	Number of Nonvested Profits Interests	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2018	9,765,439	0.08
Granted	16,143,382	0.22
Vested	(4,790,327)	0.07
Forfeited	(1,186,217)	0.12
Outstanding at December 31, 2018	19,932,277	0.19
Granted	19,643,100	0.16
Vested	(7,044,620)	0.14
Forfeited	(10,588,658)	0.21
Outstanding at December 31, 2019	21,942,099	0.18
Expected to vest at December 31, 2018	19,932,277	
Expected to vest at December 31, 2019	21,942,099	

In connection with the issuance of any profits interests, the Board will determine and set a threshold dollar amount with respect to the units, or the strike price. The strike price is determined and set as the fair value of the underlying common units on the date of the grant.

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

The Company uses an option pricing model to value profit interests. The assumptions used to value profits interests granted during the years ended December 31, 2019 and 2018 were as follows:

	<u>2019</u>	<u>2018</u>
Expected term (in years)	6.0	6.0
Risk-free rate	1.74%	2.51%
Expected volatility	72.75%	60.28%
Expected dividend yield	0.00%	0.00%

The weighted-average grant-date fair value for profits interests granted during the years ended December 31, 2019 and 2018 was \$0.16 and \$ 0.22 per unit, respectively. Compensation expense from profits interests for the years ended December 31, 2019 and 2018, was \$0.9 million and \$0.7 million, respectively. As of December 31, 2019, remaining unrecognized compensation expense related to nonvested profits interests was \$3.6 million, which is expected to be recognized over a weighted-average period of 2.2 years.

10. License, Research and Collaboration Agreements

License Agreements

Horizon Agreements

The Company entered into a license agreement on October 14, 2016 (the “Horizon Agreement”) with Horizon Discovery Ltd. (“Horizon”), which agreement pertains to a gene-edited cell line and expression vector. Under the terms of the Horizon Agreement, the Company paid a one-time only, upfront fee of £0.5 million (approximately \$0.5 million) upon execution of the agreement in October 2016. The Company may terminate the Horizon Agreement without cause at any time upon 30 days prior written notice to Horizon.

In February 2018 the Company entered two license agreements (the “Horizon SSI License Agreement” and the “Horizon Transposase License Agreement”) with Horizon, collectively referred to as the Horizon License Agreements. The Horizon SSI License Agreement pertains to certain single site integration technology and the Horizon Transposase License Agreement pertains to certain transposase technology. In June 2019, the Company exercised its’ right to terminate both agreements and no additional payments were made or are due.

The Company accounted for the acquisition of technology as an asset acquisition because it did not meet the definition of a business. The Company recorded the upfront payment as research and development expense in the consolidated statement of operations and comprehensive loss because the acquired technology represented in-process research and development and had no alternative future use. The Company recorded research and development expense of \$0 and \$0.3 million in connection with the Horizon SSI License Agreement during the years ended December 31, 2019 and 2018, respectively, and recorded research and development expense of \$0 and \$0.3 million in connection with the Horizon Transposase License Agreement during the years ended December 31, 2019 and 2018, respectively.

Collaboration Agreements

Adimab Agreement

The Company entered into a collaboration agreement with Adimab, LLC on October 16, 2014 which was subsequently amended on December 6, 2014 and February 11, 2015. As of December 31, 2019, future milestone payments in connection with this agreement amounted to \$3.5 million. The agreement also includes provisions

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

for payment of 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 Company recorded research and development expense of \$1.5 million and \$0 in connection with this agreement during the years ended December 31, 2019 and 2018, respectively.

Other License and Research Agreements

During 2019 and 2018, the Company entered into several license agreements with various academic and health care institutions to in-license certain intellectual property rights and know-how relevant to its programs. As part of the consideration related to these license agreements, the Company made cash payments of \$0.8 million and \$0.6 million during the years ended December 31, 2019 and 2018, respectively. The Company recorded \$0.8 million and \$0.4 million to research and development expense during the years ended December 31, 2019 and 2018, respectively. In addition, the Company also committed to make certain clinical and regulatory milestone payments in the aggregate of \$0.5 million associated with the in-licensed technology.

11. Commitments

Operating Leases

The Company leased office space in Hanover, NH until the lease was assigned to a third party on February 1, 2018. The Company currently leases laboratory and office space in Cambridge, MA. The Company also leases a vivarium and storage space in Cambridge, MA which was extended in June 2019 through January 2021.

All leases expire between January 31, 2020 and January 31, 2021. The future minimum rental payments under the leases as of December 31, 2019 are as follows (in thousands):

	<u>Amount</u>
Year Ending December 31,	
2020	\$ 302
2021	13
	<u>\$ 315</u>

In addition, the Company subleased one of its facilities in Cambridge, Massachusetts to an unrelated third party beginning on October 21, 2017 and expired at the end of the original lease term on December 31, 2018. The Company received approximately \$ 0.5 million in annual sublease rental income for the year ended December 31, 2018. Rental expense is recorded as an operating expense within both research and development and general and administrative expenses. Rental expense for the years ended December 31, 2019 and 2018 was \$ 1.8 million and \$1.8 million, respectively.

The sublease on the Company's main facility was set to expire on January 31, 2020. In January 2020, the sublease was extended. Refer to Note 16.

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

12. Severance Costs

The Company incurred severance costs in 2018 and 2019. The costs recorded and paid are summarized as follows for the year ended December 31, 2019 (in thousands):

Balances at December 31, 2017	\$ —
Additional severance agreements	294
Payments	<u>(74)</u>
Balances at December 31, 2018	\$ 220
Additional severance agreements	447
Payments	<u>(667)</u>
Balances at December 31, 2019	<u>\$ —</u>

13. Defined Contribution Plan

The Company has a 401(k) defined contribution plan (the “401(k) Plan”) for substantially all of its employees. Eligible employees may make pre-tax or post-tax (Roth) contributions to the 401(k) Plan up to statutory limits. The Company does not make contributions to the plan.

14. Related Parties and Related-Party Transactions

On October 16, 2014, the Company entered into a collaboration agreement with Adimab, LLC.

The Company’s co-founder has a direct ownership interest in Adimab, LLC. The Company recorded \$1.5 million and \$0 in research and development expense related to Adimab, LLC for the years ended December 31, 2019 and 2018, respectively.

On September 18, 2017, the Company entered into a software license and services agreement with StackWave, LLC. An employee of the Company is the co-founder and has a direct ownership interest in StackWave, LLC. The Company recorded software expense of \$20,000 and \$37,000 in general and administration expense related to StackWave, LLC for the years ended December 31, 2019 and 2018, respectively. The Company also recorded capitalized software of \$0.1 and \$0.3 related to StackWave, LLC for the years ended December 31, 2019 and 2018, respectively.

15. Income Taxes

Compass Therapeutics LLC is organized as a Delaware Limited Liability Company (LLC), treated as a partnership for federal and state income tax purposes. As such, members are allocated their share of the Company’s income/loss and are responsible for any federal, Massachusetts or any other state income taxes thereon. No federal or Massachusetts income taxes related to the LLC are recorded in the consolidated financial statements. The Company’s wholly owned subsidiary, 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 the consolidated financial statements.

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

The federal and state income tax provision is summarized as follows (in thousands):

	<u>2019</u>	<u>2018</u>
Current		
Federal	\$ (61)	\$ (64)
State	(30)	(39)
	<u>(91)</u>	<u>(103)</u>
Deferred		
Federal	—	—
State	—	—
Total provision for income taxes	<u>\$ (91)</u>	<u>\$ (103)</u>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for tax purposes. Significant components of the Company's deferred tax assets are as follows (in thousands):

	<u>2019</u>	<u>2018</u>
Short-Term Deferred tax asset		
Net operating losses	\$ —	\$ 26
Deferred tax asset before valuation allowance	—	26
Short-Term Valuation allowance		(26)
Net short-term deferred tax asset	<u>\$ —</u>	<u>\$ —</u>
Long-Term Deferred tax asset		
R&D and other credit carryforwards	1,511	980
Deferred tax asset before valuation allowance	1,511	980
Long-Term Valuation allowance	(1,511)	(980)
Net long-term deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which principally comprise of research and development credits. Starting in 2017, the Company is able to utilize a portion of its research and development credit against payroll taxes due to new federal tax legislation. The election was not made in 2019. The amounts listed above for 2018 are net of the portion applied against payroll. Management has considered the Company's history of losses and excess credits and concluded that it is more likely than not that the Company will not recognize all of the benefit of federal deferred tax assets and all of the benefit of state deferred tax assets. Accordingly, a short-term valuation allowance of \$0 and \$0.1 and a long-term valuation allowance of \$1.5 and \$1.0 have been established at December 31, 2019 and 2018, respectively.

The Company does not have any liabilities related to uncertain tax positions as of December 31, 2019 and 2018.

16. Subsequent Events

For its consolidated financial statements as of December 31, 2019 and for the year then ended, the Company evaluated subsequent events through June 23, 2020, the date on which those financial statements were issued, and the following subsequent events were noted.

COMPASS THERAPEUTICS LLC AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

Merger Transaction

On June 19, 2020, Olivia Ventures, Inc., Acquisition Sub, Compass Therapeutics Acquisition, Blockers, Blockers Merger Subs and Blocker Holders entered into the Merger Agreement with Compass Therapeutics LLC, pursuant to which Compass Acquisition Sub merged with and into Compass Therapeutics LLC, with Compass Therapeutics continuing as the surviving entity and Acquisition Sub' wholly-owned subsidiary, and each Blocker Merger Sub merged with and into the applicable Blocker, with each Blocker continuing as the surviving entity and Blocker Merger Subs' 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 and preferred membership units of Compass Therapeutics and 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 units who were not accredited investors, we paid an aggregate of approximately \$68 thousand in cash in consideration for cancelling such membership units 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.

The Offering

On June 19, 2020, we sold 12,096,442 shares of our common stock pursuant to the initial closing of the offering for up to 14,000,000 shares of our common stock, at a purchase price of \$5.00 per share for approximately \$54 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.

Operating Leases

On January 8, 2020, the Company extended its lease on the laboratory and office space in Cambridge, MA through January 2021. Total additional lease payments expected in 2020 and 2021 as a result of the extension were approximately \$1.8.

Coronavirus ("COVID-19")

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a pandemic which continues to spread throughout the United States and the world. The Company is monitoring the outbreak of COVID-19 and the related business and travel restrictions and changes to behavior intended to reduce its spread, in addition to the impact on its employees. The Company is not able to predict the ultimate impact that COVID -19 will have on its business; however, if the current economic conditions continue the Company will be forced to significantly scale back its business operations and its growth plans, and could ultimately have a significant negative impact on the Company.

[Table of Contents](#)

**COMPASS THERAPEUTICS LLC AND SUBSIDIARY
INDEX TO UNAUDITED FINANCIAL STATEMENTS**

	<u>Page</u>
Financial Statements (Unaudited)	F-29
Condensed Consolidated Balance Sheets (Unaudited)	F-29
Condensed Consolidated Statements of Operations (Unaudited)	F-30
Condensed Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit) (Unaudited)	F-31
Condensed Consolidated Statements of Cash Flows (Unaudited)	F-32
Notes to Unaudited Condensed Consolidated Financial Statements	F-33

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	<u>September 30,</u> <u>2020</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2019</u> <u>(Note 3)</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 55,518	\$ 25,303
Prepaid expenses and other current assets	2,314	935
Total current assets	57,832	26,238
Property and equipment, net	2,418	3,751
Restricted cash	263	263
Other assets	177	129
Total assets	<u>\$ 60,690</u>	<u>\$ 30,381</u>
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Current portion of long-term debt	\$ 7,461	\$ 5,576
Accounts payable	854	629
Accrued expenses	1,358	3,122
Derivative liability related to loan	—	494
Total current liabilities	9,673	9,821
Long-term debt, net of current portion	3,730	9,293
Total liabilities	13,403	19,114
Commitments and contingencies (Note 11)		
Convertible preferred stock—207,164,404 authorized, issued, and outstanding as of December 31, 2019. No shares authorized, issued, and outstanding as of September 30, 2020.	—	129,870
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value: 10,000,000 shares authorized and no shares issued and outstanding as of September 30, 2020; no shares issued and outstanding as of December 31, 2019	—	—
Common stock, \$0.0001 par value: 300,000,000 shares authorized; 52,120,062 and 9,073,002 shares issued at September 30, 2020 and December 31, 2019, respectively; 51,024,270 and 7,034,047 shares outstanding at September 30, 2020 and December 31, 2019, respectively	5	1
Additional paid-in-capital	190,299	3,304
Accumulated deficit	(143,017)	(121,908)
Total stockholders' equity (deficit)	47,287	(118,603)
Total liabilities and stockholders' equity (deficit)	<u>\$ 60,690</u>	<u>\$ 30,381</u>

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

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 3,670	\$ 5,979	\$ 10,498	\$ 19,146
General and administrative	5,291	2,404	9,364	8,504
Total operating expenses	<u>8,961</u>	<u>8,383</u>	<u>19,862</u>	<u>27,650</u>
Loss from operations	(8,961)	(8,383)	(19,862)	(27,650)
Other income (expense):				
Interest income	22	176	70	647
Interest expense	(212)	(312)	(730)	(944)
Change in fair value of derivative liability	—	(7)	(556)	(96)
Realized foreign exchange loss	1	—	1	(8)
Total other expense	<u>(189)</u>	<u>(143)</u>	<u>(1,215)</u>	<u>(401)</u>
Loss before income tax expense	(9,150)	(8,526)	(21,077)	(28,051)
Income tax expense	—	(26)	(32)	(81)
Net loss	<u>\$ (9,150)</u>	<u>\$ (8,552)</u>	<u>\$ (21,109)</u>	<u>\$ (28,132)</u>
Net loss per share—basic and diluted	<u>\$ (0.18)</u>	<u>\$ (1.27)</u>	<u>\$ (0.88)</u>	<u>\$ (4.26)</u>
Basic and diluted weighted average shares outstanding	<u>50,939,657</u>	<u>6,752,143</u>	<u>23,968,408</u>	<u>6,601,951</u>

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

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS'
EQUITY (DEFICIT) (UNAUDITED)
(In thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at January 1, 2020	207,164,404	\$ 129,870	7,034,047	\$ 1	\$ 3,304	\$ (121,908)	\$ (118,603)
Vesting of share-based awards	—	—	88,080	—	—	—	—
Stock-based compensation	—	—	—	—	247	—	247
Net loss	—	—	—	—	—	(6,402)	(6,402)
Balance at March 31, 2020	207,164,404	129,870	7,122,127	1	3,551	(128,310)	(124,758)
Common shares issued to former shareholders of Olivia Ventures Inc.	—	—	1,000,000	—	—	—	—
Conversion of Compass Therapeutics LLC preferred shares into common shares upon consummation of the reverse merger	(207,164,404)	(129,870)	30,629,606	3	129,867	—	129,870
Common shares issued in private placement, net of issuance costs of \$6,902	—	—	12,096,442	1	53,580	—	53,581
Payment to non-participating Compass Therapeutics LLC members upon consummation of Merger	—	—	(13,640)	—	(69)	—	(69)
Vesting of share-based awards	—	—	62,298	—	—	—	—
Stock-based compensation	—	—	—	—	183	—	183
Net loss	—	—	—	—	—	(5,557)	(5,557)
Balance at June 30, 2020	—	—	50,896,833	5	187,112	(133,867)	53,250
Adjustment to issuance costs related to June 2020 private placement	—	—	—	—	651	—	651
Vesting of share-based awards	—	—	127,437	—	—	—	—
Stock-based compensation	—	—	—	—	2,536	—	2,536
Net loss	—	—	—	—	—	(9,150)	(9,150)
Balance at September 30, 2020	—	\$ —	51,024,270	\$ 5	\$ 190,299	\$ (143,017)	\$ 47,287

	Convertible Preferred		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at January 1, 2019	207,164,404	\$ 129,870	6,355,377	\$ 1	\$ 2,389	\$ (87,164)	\$ (84,774)
Vesting of share-based awards	—	—	223,072	—	—	—	—
Share-based compensation expense	—	—	—	—	255	—	255
Net loss	—	—	—	—	—	(10,771)	(10,771)
Balance at March 31, 2019	207,164,404	129,870	6,578,449	1	2,644	(97,935)	(95,290)
Vesting of share-based awards	—	—	105,127	—	—	—	—
Share-based compensation expense	—	—	—	—	185	—	185
Net loss	—	—	—	—	—	(8,809)	(8,809)
Balance at June 30, 2019	207,164,404	129,870	6,683,576	1	2,829	(106,744)	(103,914)
Vesting of share-based awards	—	—	228,407	—	—	—	—
Share-based compensation expense	—	—	—	—	249	—	249
Net loss	—	—	—	—	—	(8,552)	(8,552)
Balance at September 30, 2019	207,164,404	\$ 129,870	6,911,983	\$ 1	\$ 3,078	\$ (115,296)	\$ (112,217)

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

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(In thousands)

	For the Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (21,109)	\$ (28,132)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,335	1,599
Loss on disposal of equipment	8	5
Noncash interest expense	72	93
Share-based compensation	2,966	689
Change in fair value of derivative liability	556	96
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,379)	228
Other long-term assets	25	(26)
Accounts payable	194	(1,103)
Accrued expenses	(1,848)	401
Settlement of derivative liability	(1,050)	—
Net cash used in operating activities	<u>(20,230)</u>	<u>(26,150)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(23)	(281)
Proceeds from sale of equipment	55	—
Net cash provided by (used in) investing activities	<u>32</u>	<u>(281)</u>
Cash flows from financing activities:		
Proceeds from issuance of common units	60,482	—
Issuance costs from issuance of common units	(6,319)	—
Repayment of borrowings under loan	(3,750)	—
Net cash provided by financing activities	<u>50,413</u>	<u>—</u>
Net change in cash, cash equivalents and restricted cash	30,215	(26,431)
Cash, cash equivalents and restricted cash at beginning of period	25,566	57,773
Cash, cash equivalents and restricted cash at end of period	<u>\$ 55,781</u>	<u>\$ 31,342</u>
Supplemental disclosure of cash flow information		
Cash paid for interest	<u>\$ 686</u>	<u>851</u>
Supplemental disclosure of financing activities		
Conversion of preferred units	<u>\$ 129,870</u>	<u>\$ —</u>
Deferred offering costs included in accrued expenses	<u>\$ (116)</u>	<u>\$ —</u>

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

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

1. Nature of Business and Basis of Presentation

Compass Therapeutics, Inc. (“Compass” or the “Company”) is a clinical-stage biopharmaceutical company developing proprietary antibody therapeutics intended to engage the immune system to treat both solid tumors and hematological malignancies. The Company’s immuno-oncology product candidates include a clinical-stage monoclonal antibody and a portfolio of bispecific antibodies. The Company was incorporated as Olivia Ventures, Inc. (“Olivia”) in the State of Delaware on March 20, 2018. Prior to the Merger (as defined below), Olivia was a “shell company” (as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended).

On June 17, 2020, the Company’s Board of Directors and the Company’s pre-Merger (defined below) stockholders approved an amended and restated certificate of incorporation, which, among other things, increased authorized capital stock from 50,000,000 shares of common stock par value \$0.0001 and 5,000,000 shares of preferred stock, par value \$0.0001 per share, to 300,000,000 shares of common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share.

On June 17, 2020, the Company completed a merger (the “Merger”) of a wholly-owned subsidiary Compass Therapeutics LLC (“Compass LLC”) pursuant to an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”), by and among the Company, Olivia Ventures, Inc., Acquisition Sub, Compass Therapeutics, Blockers, Blockers Merger Subs and Blocker Holders and, as a result of, Compass LLC became a wholly-owned subsidiary of the Company.

At the effective time of the Merger and the applicable effective time of each Blocker Merger, collectively, the Effective Time, an aggregate of 31,627,139 shares of its common stock were issued to holders of common membership interests of Compass LLC (including common membership interests issued upon the conversion of preferred membership interests) and 7,428,217 shares of its common stock were issued to the holders of equity interests of the Blockers. The issuances of shares of the Company’s common stock to the security holders of Compass LLC and the Blockers are collectively referred to as the Share Conversion.

In addition, 2,930,836 shares of the Company’s common stock were reserved for issuance under its 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 the Company’s common stock held by pre-Merger stockholders of Olivia Ventures, Inc. were forfeited and surrendered for cancellation, or the Stock Forfeiture. No fractional shares of the Company’s common stock were issued in connection with the Merger, and holders of Compass LLC Units received cash in lieu thereof.

The Merger and the Blocker Mergers were treated as a recapitalization and reverse acquisition for financial reporting purposes. Compass Therapeutics is considered the acquirer for accounting purposes, and the Company’s historical financial statements before the Merger have been replaced with the historical financial statements of Compass Therapeutics in this and future filings with the SEC. As a result, the vested and outstanding common units held by Compass LLC members have been presented as outstanding shares of the Company’s common stock for all periods presented. All outstanding preferred units of Compass LLC are presented as convertible preferred stock for all periods and until such units were converted into shares of the Company’s common stock at the time of the Merger.

On June 19, 2020, the Company completed a private placement and sold 12,096,442 shares of its common stock at a purchase price of \$5.00 per share and received net proceeds of \$54.2 million.

The Company is subject to risks and uncertainties common to companies in the biotechnology and pharmaceutical industries. There can be no assurance that the Company’s research and development will be

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

successfully completed, that adequate protection for the Company's technology will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

2. Liquidity, Uncertainties and Going Concern

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued.

Since its inception, the Company has funded its operations primarily with proceeds from the sale of its equity securities and borrowings under loan agreements. The Company has incurred recurring losses since its inception and had an accumulated deficit of \$143.0 million at September 30, 2020. The Company expects to continue to generate operating losses for the foreseeable future. The Company expects that its cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into the first quarter of 2022. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

In December 2019, a novel strain of coronavirus ("COVID-19") was reported to have surfaced in Wuhan, China. As of May 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 the Company's 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 the Company's 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.

Due to the evolving and uncertain global impacts of the COVID-19 pandemic, the Company cannot precisely determine or quantify the impact this pandemic will have on its business operations for the remainder of fiscal 2020. The extent to which COVID-19 may impact the Company's results of operations 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 ongoing and planned clinical trials, the Company has 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 the Company's development plans, including the initiation of planned clinical trials and its ability to conduct ongoing clinical trials. There may also be local orders affecting one or more trial

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

sites, which may trigger mandated changes to the Company's 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, employees and business operations, personnel at 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 the Company's product candidates, and sales and marketing activities for any product candidates for which the Company may receive marketing approval in the U.S. or other geographies in the future.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements are presented in U.S. dollars and have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and as amended by Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of September 30, 2020 and its results of operations and changes in convertible preferred stock and stockholders' equity (deficit) for the three and nine months ended September 30, 2020 and 2019 and cash flows for the nine months ended September 30, 2020 and 2019. Operating results for the nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020.

The condensed consolidated balance sheet at December 31, 2019 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements. These unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements of Compass Therapeutics LLC and related footnotes for the year ended December 31, 2019, included as Exhibit 99.1 in the Company's Form 8-K filed with the SEC on June 23, 2020.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Compass Therapeutics, Inc., and its wholly-owned subsidiaries Compass Therapeutics LLC and Compass Therapeutics Advisors Inc. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual of research and development expenses, the valuation of the embedded derivative, the valuation of common stock and estimates associated with stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from those estimates. Changes in estimates are recorded in the period that they become known.

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

Segment Information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company has one operating segment. The Company's chief operating decision-maker, its chief executive officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources. All of the Company's long-lived assets are held in the United States.

Cash and Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash with original maturities of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held in money market funds. Cash equivalents are stated at cost, which approximates market value. Cash equivalents consisted of money market funds of \$52.2 million and \$22.8 million at September 30, 2020 and December 31, 2019, respectively.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and restricted cash. The Company maintains its cash, cash equivalents and restricted cash with financial institutions that management believes to be of high-credit quality. The Company has not experienced any losses related to its cash, cash equivalents and restricted cash.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization are recorded using the straight-line method over the estimated useful lives of the related assets as follows:

Asset Classification	Estimated Useful Life
Equipment	5 years
Furniture and fixtures	7 years
Software	5 years
Leasehold improvements	Lesser of estimated useful life or lease term

Estimated useful lives are periodically assessed to determine if changes are appropriate. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation or amortization are eliminated from the condensed consolidated balance sheet and any resulting gains or losses are included in the condensed consolidated statement of operations in the period of disposal. Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service. Assets held under capital leases are stated at the lesser of the present value of future minimum lease payments or the fair value of the leased asset at the inception of the lease. Amortization of assets held under capital leases is computed using the straight-line method over the shorter of the estimated useful life of the asset or the period of the related lease.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized in the condensed consolidated statements of operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. The Company did not record any impairment losses on long-lived assets during the nine months ended September 30, 2020 and 2019.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets and liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

An entity may choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected are reported in earnings.

The Company's cash equivalents are carried at fair value according to the fair value hierarchy described above and were determined based on Level 1 measurements (see Note 4). The Company's restricted cash is carried at fair value according to the fair value hierarchy described above and were determined based on Level 2 measurements (see Note 4). The carrying values of other current assets and accounts payable approximate their fair value due to the short-term nature of these assets and liabilities. The carrying values of the Company's loan approximated its fair value as of September 30, 2020 and December 31, 2019 due to its variable interest rate. The fair value of the loan related embedded derivative (see Note 4) was determined based on Level 3 measurements.

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

Research and Development Costs

Costs associated with internal research and development and external research and development services, including drug development and preclinical studies, are expensed as incurred. Research and development expenses include costs for salaries, employee benefits, subcontractors, facility-related expenses, depreciation and amortization, stock-based compensation, third-party license fees, laboratory supplies, and external costs of outside vendors engaged to conduct discovery, preclinical and clinical development activities and clinical trials as well as to manufacture clinical trial materials, and other costs. The Company recognizes external research and development costs based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its service providers.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such prepaid expenses are recognized as an expense when the goods have been delivered or the related services have been performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

Costs associated with licenses of technology acquired as part of collaborative arrangements are expensed as incurred and are generally included in research and development expense in the condensed consolidated statements of operations if it is determined the license has no alternative future use.

Accrued Research and Development Expenses

The Company has entered into various research and development and other agreements with commercial firms, researchers, universities and others for provisions of goods and services. These agreements are generally cancelable, and the related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Stock-Based Compensation

Prior to the Merger, Compass Therapeutics LLC issued Class A and Class C common units to various employees, directors and consultants. The units constituted "profits interests" for tax purposes and were accounted for as share-based payment arrangements. Upon consummation of the Merger, all outstanding vested units were converted into shares of common stock and all outstanding unvested units were converted into shares of restricted stock that continue to vest over the remaining term of the original award. Subsequent to the Merger, the Company has granted stock options to various employees, directors and consultants.

The Company recognizes the grant-date fair value of stock-based awards issued to employees and nonemployee board members as compensation expense on a straight-line basis over the vesting period of the award. The Company uses the Black-Scholes option pricing model to determine the grant-date fair value of stock options and adjusts expense for forfeitures in the periods they occur.

Net Loss per Share

Basic loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during each period. Diluted loss per share includes the effect, if any, from the potential

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

exercise or conversion of securities, such as convertible preferred stock, stock options, unvested restricted stock and common stock warrants that would result in the issuance of incremental shares of common stock. In computing the basic and diluted net loss per share, the weighted average number of shares remains the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities outstanding as of September 30, 2020 and 2019 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	September 30,	
	2020	2019
Convertible preferred stock	—	30,629,606
Stock options	1,625,469	—
Nonvested restricted stock	1,095,792	1,916,891
Common stock warrants	—	3,114,145
Total	2,721,261	35,660,642

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which requires a lessee to record a right-of-use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the condensed consolidated financial statements as its date of initial application. If an entity chooses the second option, the transition requirements for existing leases also apply to leases entered into between the date of initial application and the effective date. The standard is effective for the Company beginning January 1, 2021, with early adoption permitted. The Company plans to adopt this standard on January 1, 2021 and is currently evaluating the expected impact that the standard could have on its financial position and results of operations upon adoption.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurements*, which changes the fair value measurement disclosure requirements of ASC Topic 820. The goal of the ASU is to improve the effectiveness of ASC Topic 820's disclosure requirements. The Company adopted this guidance on January 1, 2020 and was not material to its condensed consolidated financial statements and related disclosures.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606* ("ASU 2018-18"). The amendments in this update clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue when the collaborative arrangement participant is a customer in the context of a unit of account and precludes recognizing as revenue consideration received from a collaborative arrangement participant if the participant is not a customer. The standard is effective for the Company beginning January 1, 2021. The Company is currently evaluating the potential impact ASU 2018-18 may have on its financial position and results of operations upon adoption.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify the accounting for income taxes.

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The new standard will be effective beginning January 1, 2022. The Company does not expect the adoption of ASU 2019-12 to have a material impact on its financial position and results of operations upon adoption.

4. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurements as of September 30, 2020 Using:			Fair Value
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets				
Cash equivalents—money market funds	\$ 52,175	\$ —	\$ —	\$ 52,175
Restricted cash	—	263	—	263
Total assets	<u>\$ 52,175</u>	<u>\$ 263</u>	<u>\$ —</u>	<u>\$ 52,438</u>
Liabilities				
Derivative liability related to loan	\$ —	\$ —	\$ —	\$ —
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

	Fair Value Measurements as of December 31, 2019 Using:			Fair Value
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets				
Cash equivalents—money market funds	\$ 22,784	\$ —	\$ —	\$ 22,784
Restricted cash	—	263	—	263
Total assets	<u>\$ 22,784</u>	<u>\$ 263</u>	<u>\$ —</u>	<u>\$ 23,047</u>
Liabilities				
Derivative liability related to loan	\$ —	\$ —	\$ 494	\$ 494
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 494</u>	<u>\$ 494</u>

Valuation of Derivative Liability

The Company's derivative liability was comprised of the contingent interest rate reset features and a contingent feature to pay a success fee upon the occurrence of certain liquidity events, each of which met the definition of a derivative instrument, which terms are included in the loan and security agreement (refer to Note 7). The Company classified these instruments as a liability on the condensed consolidated balance sheets

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

because these features were not clearly and closely related to its host instrument and met the definition of a derivative. The derivative liability was initially recorded at fair value upon issuance of the loan and was being subsequently remeasured to fair value at each reporting date. Changes in the fair value of the derivative liability were recognized as a component of other income (expense), net in the condensed consolidated statements of operations. The success fee was paid in full following the closing of the Merger in June 2020.

The fair value of the derivative liability recognized was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the derivative liability was determined using the probability-weighted expected return method, which considered as inputs the type, timing and probability of occurrence of a change-of-control event, the future equity financing and cash settlement of the loans; the potential amount of the payment under each of these potential settlement scenarios; and the risk-adjusted discount rate reflecting the expected risk profile for each of the potential settlement scenarios.

The following table provides a roll forward of the aggregate fair values of the Company's derivative liability (in thousands):

	Derivative Liability
Balance at December 31, 2019	\$ 494
Change in fair value	556
Payment of success fee	(1,050)
Balance at September 30, 2020	\$ —

5. Property and Equipment

Property and equipment consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Equipment	\$ 7,040	\$ 7,230
Furniture and fixtures	629	629
Leasehold improvements	896	896
Software	912	669
Assets not yet placed in service	—	230
Total property and equipment—at cost	9,477	9,654
Less: Accumulated depreciation	(7,059)	(5,903)
Property and equipment, net	\$ 2,418	\$ 3,751

Total depreciation and amortization expense for three months ended September 30, 2020 and 2019, was \$0.4 million and \$0.5 million, respectively. Total depreciation and amortization expense for nine months ended September 30, 2020 and 2019, was \$1.3 million and \$1.6 million, respectively.

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

6. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Compensation and benefits	\$ 605	\$ 1,759
Research and development expenses	26	249
Legal and professional fees	507	417
Sales taxes	—	554
Other	220	143
Total accrued expenses	<u>\$ 1,358</u>	<u>\$ 3,122</u>

7. Loan Payable

The aggregate principal amount of debt outstanding consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Current portion of debt	\$ 7,500	\$ 5,625
Less: unamortized debt discount	(39)	(49)
Current portion of debt, net of debt discount	<u>\$ 7,461</u>	<u>\$ 5,576</u>
Long-term debt, net of current portion	\$ 3,750	\$ 9,375
Less: unamortized debt discount	(20)	(82)
Long-term debt, net of current portion	<u>\$ 3,730</u>	<u>\$ 9,293</u>

The Company entered into, and subsequently amended, a term loan facility with Pacific Western Bank, Inc. (“PWB”), and received \$15.0 million debt proceeds. The loans bear interest at the greater of (i) 6.25% and (ii) the prime rate plus an applicable margin of 2.0%. The interest rate was 6.25% at September 30, 2020. In an event of default, as defined in the agreement, the interest rate applicable to borrowings would be increased by 5.0%. The Company made interest-only payments through March 31, 2020. Beginning in April 2020, the Company is obligated to make equal monthly principal payments of \$625,000 through March 31, 2022 when the notes mature. The loan agreement allows for prepayment of the outstanding principal at any time, subject to a prepayment charge that is dependent on the prepayment date.

The debt agreement contained provisions whereby the Company was obligated to pay a success fee of \$1.1 million upon the achievement of certain liquidity events. Upon consummation of the Merger, the Company success fee payment became due and was paid in its entirety in June 2020.

The 2018 Credit Facility contains a negative pledge on the Company’s intellectual property 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, the Company must maintain a minimum cash balance of \$6.0 million beginning in April 2020. In the event of default under the 2018 Credit Facility, the Company would be required to pay interest on principal and all other due and unpaid obligations at the current rate in effect plus 5%.

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

The borrowings are collateralized by substantially all of the Company's assets, excluding intellectual property, and contains affirmative and negative covenants including restrictions on the Company's ability to incur additional indebtedness, pay dividends, encumber its property, or engage in certain fundamental business transactions, such as mergers or acquisitions of other businesses. The Company must maintain a minimum cash balance of \$6.0 million beginning in April 2020. The Company was in compliance with its covenants as of September 30, 2020.

The Company recognized interest expense of \$0.2 million and \$0.3 million during the three months ended September 30, 2020 and 2019 and \$0.7 million and \$0.9 million during the nine months ended September 30, 2020 and 2019, respectively.

As of September 30, 2020, the aggregate minimum future principal payments due in connection with the 2018 Loan Agreement, as amended, are as follows (in thousands):

Year Ending December 31,	
2020	\$ 1,875
2021	7,500
2022	1,875
	<u>\$ 11,250</u>

8. Convertible Preferred Stock and Stockholders' Equity (Deficit)

Convertible Preferred Stock

In connection with the Merger, as discussed in Note 1, the Company issued 30,629,606 shares of its common stock to holders of convertible preferred interests of Compass Therapeutics LLC. No convertible preferred securities were outstanding as of September 30, 2020.

As of December 31, 2019, convertible preferred stock consisted of the following shares outstanding:

<u>Preferred Stock</u>	<u>Shares Issued and Outstanding</u>
Series A-1	64,704,832
Series A-2	36,782,734
Series A-3	23,467,151
Series A-4	15,253,415
Series A4B	22,216,583
Series A-5	44,739,689
	<u>207,164,404</u>

Common Stock

In connection with the Merger, as discussed in Note 1, the Company issued 1,000,000 shares of common stock to the former shareholders of Olivia Ventures Inc. The Company paid \$69,000 to several nonaccredited investors of Compass Therapeutics LLC in lieu of issuing shares. In addition, 2,930,836 shares of the Company's common stock were reserved for issuance under the 2020 Stock Option and Incentive Plan.

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

The Company also sold 12,096,442 shares of its common stock pursuant to the closing of a private placement offering at a purchase price of \$5.00 per share.

9. Stock-Based Compensation

Stock-based compensation expense for the three and nine months ended September 30, 2020 and 2019 was classified in the consolidated statement of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	\$ 374	\$103	\$ 486	\$278
General and administrative	2,162	146	2,480	411
Total	<u>\$2,536</u>	<u>\$249</u>	<u>\$2,966</u>	<u>\$689</u>

Estimating Fair Value of Equity Awards

The fair value of each equity award was determined by the Company on the date of grant and by using the methods and assumptions discussed below. Certain of these inputs are subjective and generally require judgment to determine.

Expected Term: The expected term of the equity award represents the weighted average period the award is expected to be outstanding. The Company uses the simplified method for estimating the expected term as provided by the Securities and Exchange Commission. The simplified method calculates the expected term as the average time to vesting and the contractual life of the award.

Expected volatility—Due to the Company's limited operating history and lack of company-specific historical or implied volatility, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available.

Risk-free interest rate—The risk-free rate assumption is based on the U.S. Treasury instruments, the terms of which were consistent with the expected term of the Company's equity award.

Expected dividend—The Company has not paid and does not intend to pay dividends.

Following the closing of the Merger and upon establishing a public trading market for the Company's securities, the fair value of the Company's common stock used to value equity awards will be based on the closing price of the Company's common stock as reported on the date of the grant.

Restricted Stock

Prior to the Merger, Compass LLC maintained an incentive pool of unit-based awards that were granted to board members, employees and consultants and accounted for as unit-based compensation. Upon consummation of the Merger, all outstanding vested profits interests units were converted into shares of the Company's common stock. Unvested units were converted into restricted shares of the Company's common stock and will continue to vest under the same terms as the original profits interests.

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

A summary of the Company's restricted share activity during the nine months ended September 30, 2020 is as follows:

Weighted Average Grant Date Fair Value	Shares	Estimated Fair Value Per Share
Nonvested, January 1, 2020	2,038,955	\$ 2.04
Granted	879	\$ 2.34
Vested	(277,815)	\$ 1.51
Forfeited or canceled	(666,227)	\$ 1.78
Nonvested, September 30, 2020	<u>1,095,792</u>	<u>\$ 2.34</u>

The weighted-average grant-date fair value for Compass LLC profits interests granted was \$2.34 per unit. No restricted share awards have been granted following the Merger. As of September 30, 2020, remaining unrecognized compensation cost related to unvested restricted stock awards to be recognized in future periods totaled \$1.8 million, which is expected to be recognized over a weighted average period of 1.9 years.

The fair value of each profits interest was estimated on the date of grant using the weighted average assumptions in the table below:

	Nine Months Ended September 30,	
	2020	2019
Expected term (in years)	6.0	6.0
Risk-free rate	0.36%	1.75%
Expected volatility	140.45%	65.06%
Expected dividend yield	0%	0%

Stock Options

In June 2020, the Company's board of directors adopted the 2020 Stock Option and Incentive Plan (the "2020 Plan") and reserved 2,930,836 shares of common stock for issuance under this plan and subject to automatic annual increases as defined in the plan. As of September 30, 2020, 1,305,367 shares remain available for future grant.

The 2020 Plan authorizes the board of directors or a committee of the board to grant incentive stock options, nonqualified stock options and restricted stock awards to eligible officers, employees, consultants and directors of the Company. Options generally vest over a period of four years and have a contractual life of ten years from the date of grant.

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

The following table summarizes the stock option activity for the 2020 Plan:

	Number of Nonvested Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (in years)
Outstanding at January 1, 2020	—	\$ —	
Granted	1,633,000	\$ 5.00	
Exercise	—	\$ —	
Forfeited/cancelled	(7,531)	\$ 5.00	
Outstanding at September 30, 2020	<u>1,625,469</u>	\$ 5.00	9.9
Vested at September 30, 2020	<u>647,707</u>	\$ 5.00	9.8

For the nine months ended September 30, 2020, the weighted average grant date fair value for options granted was \$3.42. The aggregate intrinsic value for options vested and outstanding as of and for the nine months ended September 30, 2020 was de minimis. As of September 30, 2020, the unrecognized compensation cost related to outstanding options was \$3.3 million, expected to be recognized over a weighted average period of approximately 2.1 years.

The weighted average assumptions used in the Black-Scholes option pricing model to determine the fair value of stock options granted to employees and directors during the nine months ended September 30, 2020 were as follows:

	September 30, 2020
Expected term (in years)	5.4
Risk-free rate	0.22%
Expected volatility	86.2%
Expected dividend yield	0.00%

10. License, Research and Collaboration Agreements

Collaboration Agreements

Adimab Agreement

The Company entered into a collaboration agreement with Adimab, LLC on October 16, 2014. As of September 30, 2020, future milestone payments in connection with this agreement amounted to \$2.0 million. The agreement also includes provisions for payment of royalties at rates ranging in the single digits as a percentage of future net sales within a specified term from the first commercial sale. There were no milestone payments made during the three and nine months ended September 30, 2020. The Company made milestone payments of \$1.0 million and \$1.5 million in research and development during the three and nine months ended September 30, 2019, respectively, upon filing an IND for its product candidates associated with this license and first dosing of patient.

Other License and Research Agreements

The Company has entered into several license agreements with various academic and healthcare institutions to in-license certain intellectual property rights and know-how relevant to its programs. As part of the

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

consideration related to these license agreements, the Company made cash payments of \$63,000 and \$0.2 million during the three and nine months ended September 30, 2020, respectively.

The Company recorded research and development expense of \$64,000 and \$79,000 during the three months ended September 30, 2020 and 2019, respectively, and \$0.2 million and \$0.4 million during the nine months ended September 30, 2020 and 2019, respectively. In addition, the Company also committed to make certain clinical and regulatory milestone payments in the aggregate of \$0.5 million associated with the in-licensed technology.

11. Commitments and Contingencies

Operating Leases

The Company leases laboratory and office space in Cambridge, MA. The Company also leases a vivarium and storage space in Cambridge, MA. The leases expire January 31, 2021. The lease agreements have annual scheduled payment increases and the Company is recognizing the rent expense on a straight-line basis over the lease term. Rental expense was \$0.5 million and \$0.5 million for the three months ended September 30, 2020 and 2019, respectively, and \$1.5 million and \$1.4 million for the nine months ended September 30, 2020 and 2019, respectively.

The future minimum rental payments under the leases as of September 30, 2020 are as follows:

Year Ending December 31,	Amount
2020	\$ 481
2021	160
	<u>\$ 641</u>

12. Related Parties and Related-Party Transactions

On October 16, 2014, the Company entered into a collaboration agreement with Adimab, LLC. The Company's co-founder has a direct ownership interest in Adimab, LLC. The Company recorded research and development expense of \$0 million and \$1.5 in connection with this agreement during nine months ended September 30, 2020 and 2019, respectively.

On September 18, 2017, the Company entered into a software license and services agreement with StackWave, LLC. A former employee of the Company is the co-founder and has a direct ownership interest in StackWave, LLC. The Company recorded research and development expense of \$17,000 for the nine months ended September 30, 2020 and capitalized software of \$0.2 million and \$0.7 million for the nine months ended September 30, 2020 and 2019, respectively.

9,000,000

Common Stock



—————
PRELIMINARY PROSPECTUS
—————

Joint Book-Running Managers

Citigroup

Credit Suisse

Stifel

—————
Co-Manager

Raymond James

PART II
INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated fees and expenses payable by us in connection with the offering of the securities being registered.

SEC registration fee	\$ 6,776
FINRA filing fee	9,815
Accounting fees and expense	75,000
Nasdaq listing fee	75,000
Legal fees and expenses	275,000
Transfer agent and registrar fees	5,000
Miscellaneous	53,409
Total	<u>\$ 500,000</u>

Item 14. Indemnification of Directors and Officers.

We are incorporated under the laws of the State of Delaware. Section 145 of the DGCL provides that a Delaware corporation may indemnify any persons who were, are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation, or is or was serving at the request of such corporation as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who were, are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses (including attorneys' fees) actually and reasonably incurred.

Our amended and restated certificate of incorporation provides that to the fullest extent permitted by the DGCL, a director shall not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director. Our amended and restated bylaws provide that we shall indemnify and hold harmless our directors and officers to the fullest extent permitted by applicable law, except that we will not be required to indemnify or hold harmless any director or officer in connection with any proceeding initiated by such person unless the proceeding was authorized by our board of directors. Under our amended and restated bylaws, such rights shall not be exclusive of any other rights acquired by directors and officers, including by agreement.

Our amended and restated bylaws provide that we will pay expenses to any director or officer prior to the final disposition of the proceeding; provided, however, that such advancements shall be made only upon receipt

[Table of Contents](#)

of an undertaking by such director or officer to repay all amounts advanced if it should be ultimately determined that such director or officer is not entitled to indemnification under the amended and restated bylaws of or otherwise.

Section 174 of the DGCL provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

In addition to the indemnification obligations required by our amended and restated certificate of incorporation and amended and restated bylaws, we have entered into indemnification agreements with each of our directors and officers. These agreements provide for the indemnification of our directors and executive officers for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought or threatened to be brought against them by reason of the fact that they are or were our agents.

As a condition to the Merger, we also entered into a Pre-Merger Indemnity Agreement with our former officers and directors, pursuant to which we agreed to indemnify such former officers and directors for actions taken by them in their official capacities relating to the consideration, approval and consummation of the Merger and certain related transactions.

We expect to obtain general liability insurance that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

The above provisions may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. The provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. We believe that these amended and restated certificate of incorporation provisions, amended and restated bylaw provisions, indemnification agreements and the insurance are necessary to attract and retain qualified persons as directors and officers.

At present, there is no pending litigation or proceeding involving any of our directors or officers where indemnification will be required or permitted. We are not aware of any threatened litigation or proceedings that might result in a claim for such indemnification.

Item 15. Recent Sales of Unregistered Securities

Sales of Unregistered Securities of Compass Therapeutics, Inc.

Set forth below is information regarding shares of our common stock issued within the past three years that were not registered under the Securities Act:

- On June 17, 2020, pursuant to the terms of the Merger Agreement, all of the common membership interests of Compass OpCo (including common membership interests issued upon the conversion of preferred membership interests) held by accredited investors were converted into an aggregate of 39,055,356 shares of our common stock. These transactions were exempt from registration under

Table of Contents

Section 4(a)(2) of the Securities Act as not involving any public offering or Regulation D promulgated thereunder. None of the securities were sold through an underwriter and, accordingly, there were no underwriting discounts or commissions involved.

- On June 19, 2020, in connection with the initial closing of the Private Placement, we issued an aggregate of 12,096,442 shares of common stock at a price of \$5.00 per share for aggregate gross consideration of approximately \$60.5 million (before deducting placement agent fees and total expenses of approximately \$6.3 million) to 110 accredited investors.

The transactions described in paragraphs A, B and C were exempt from registration under Section 4(a)(2) of the Securities Act (or Rule 506 of Regulation D) as not involving any public offering.

Sales of Unregistered Securities of Compass Therapeutics LLC

Set forth below is information regarding securities of Compass OpCo sold or issued from January 1, 2017 through immediately prior to the consummation of the Merger that were not registered under the Securities Act. The following description is historical and has not been adjusted to give effect to the Merger:

- (A) In July 2017 and December 2017, Compass OpCo issued an aggregate of 22,216,583 Series A-4B preferred membership interests to accredited investors at a price per unit of \$0.9834 for aggregate gross proceeds of approximately \$21.8 million.
- (B) In June 2018, Compass OpCo issued an aggregate of 44,739,689 Series A-5 preferred membership interests to accredited investors at a price per unit of \$1.10 for aggregate gross proceeds of approximately \$49.2 million.
- (C) Compass OpCo issued an aggregate of 21,511,739 incentive units to directors, officers, employees and consultants in connection with the provision of services to Compass OpCo.

The transactions described under (A) and (B) above were exempt from registration under Section 4(a)(2) of the Securities Act (or Rule 506 of Regulation D) as not involving any public offering. The grants of incentive units described under (C) above were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 of the Securities Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701.

Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about the Company and Compass OpCo. None of the securities described in this Item 15 were sold through an underwriter and, accordingly, there were no underwriting discounts or commissions involved.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

The exhibit index attached hereto is incorporated herein by reference.

(b) Financial Statement Schedules

All schedules have been omitted because the information required to be set forth in the schedules is either not applicable or is included in our financial statements or notes to those financial statements.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act;

Table of Contents

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) Each prospectus filed pursuant to Rule 424(b) as part of the registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
1.1	Form of Underwriting Agreement
2.1	Agreement and Plan of Merger, dated June 17, 2020, by and among the Olivia Ventures, Inc., Compass Acquisition LLC, Compass Therapeutics LLC, BBV International Compass Inc., Biomatics—Compass, Inc., CHI II Blocker LLC, OrbiMed Private Investments V—KA (Blocker), Inc., Eight Roads Investments, Biomatics Capital Partners, L.P., Cowen Healthcare Investments II LP, CHI EF II LP, and OrbiMed Private Investments V—KA (Feeder), LP (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)
3.1	Certificate of Merger relating to the merger of Compass Acquisition LLC with and into Compass Therapeutics LLC, filed with the Secretary of State of the State of Delaware on 17, 2020 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)
3.2	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)
3.3	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)
4.1†	Specimen Certificate for Common Stock
5.1	Opinion of Goodwin Procter LLP
10.1*	2020 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)
10.2*	2020 Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)
10.3*	Offer letter, dated November 28, 2017, between Vered Bisker-Leib and Compass Therapeutics LLC (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)
10.4*	Form of Indemnification Agreement (directors) (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)
10.5*	Form of Indemnification Agreement (executive officers) (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)
10.6*	Form of Pre-Merger Indemnification Agreement (directors and executive officers) (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)
10.7	Registration Rights Agreement, dated June 19, 2020, by and among Compass Therapeutics, Inc. and the parties thereto (incorporated by reference to Exhibit 10.7 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)
10.8	Subscription Agreement, dated June 19, 2020, by and between Compass Therapeutics, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.8 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)
10.9**	Amended and Restated Collaboration Agreement, dated February 11, 2015, by and between Adimab LLC and Kairos Biologics Foundation LLC (incorporated by reference to Exhibit 10.9 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)

Table of Contents

<u>Exhibit</u>	<u>Description</u>
10.10	<u>Loan and Security Agreement, dated March 30, 2018, by and between Pacific Western Bank, Inc., Compass Therapeutics, LLC and Compass Therapeutics Advisors, Inc. (incorporated by reference to Exhibit 10.10 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)</u>
10.11	<u>First Amendment to Loan and Security Agreement, dated September 26, 2018, by and between Pacific Western Bank, Inc., Compass Therapeutics, LLC and Compass Therapeutics Advisors, Inc. (incorporated by reference to Exhibit 10.11 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)</u>
10.12	<u>Second Amendment to Loan and Security Agreement, dated March 8, 2019, by and between Pacific Western Bank, Inc., Compass Therapeutics, LLC and Compass Therapeutics Advisors, Inc. (incorporated by reference to Exhibit 10.12 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)</u>
10.13	<u>Third Amendment to Loan and Security Agreement, dated October 29, 2019, by and between Pacific Western Bank, Inc., Compass Therapeutics, LLC and Compass Therapeutics Advisors, Inc. (incorporated by reference to Exhibit 10.13 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)</u>
10.14	<u>Sublease Agreement, dated July 29, 2016, by and between Horizon Discovery, Inc. and Compass Therapeutics, LLC (incorporated by reference to Exhibit 10.14 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)</u>
10.15	<u>Sublease Modification Agreement, dated January 17, 2018, by and between Horizon Discovery, Inc. and Compass Therapeutics, LLC (incorporated by reference to Exhibit 10.15 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)</u>
16.1	<u>Letter from Raich Ende Malter & Co. LLP as to the change in certifying accountant, dated as of November 9, 2020</u>
21.1	<u>Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Current Report on Form 8-K filed with the SEC on June 23, 2020)</u>
23.1	<u>Consent of CohnReznick LLP, independent registered public accounting firm</u>
23.2	<u>Consent of Goodwin Procter LLP (included in Exhibit 5.1)</u>
24.1	<u>Power of Attorney (included on the signature page hereto)</u>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document

* Indicates a management contract or any compensatory plan, contract or arrangement.

** Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the SEC.

*** To be filed by amendment.

† Previously filed.

Compass Therapeutics, Inc.

[•] Shares¹
Common Stock
(\$0.0001 par value)

Underwriting Agreement

New York, New York
[•], 2020

Citigroup Global Markets Inc.

Credit Suisse Securities (USA) LLC

Stifel, Nicolaus & Company, Incorporated
As Representatives of the several Underwriters,

c/o Citigroup Global Markets Inc.
388 Greenwich Street
New York, New York 10013

c/o Credit Suisse Securities (USA) LLC
11 Madison Avenue
New York, New York 10010

c/o Stifel, Nicolaus & Company, Incorporated
787 7th Avenue, 11th Floor
New York, NY 10019

Ladies and Gentlemen:

Compass Therapeutics, Inc., a corporation organized under the laws of the State of Delaware (the "Company"), proposes to sell to the several underwriters named in Schedule I hereto (the "Underwriters"), for whom you (the "Representatives") are acting as representatives, [•] shares of common stock, \$[•] par value ("Common Stock") of the Company (said shares to be issued and sold by the Company being hereinafter called the "Underwritten Securities"). The Company also proposes to grant to the Underwriters an option to purchase up to [•] additional shares of Common Stock solely to cover over-allotments, if any (the "Option Securities;" the Option Securities, together with the Underwritten Securities, being hereinafter called the "Securities"). To the extent there are no additional Underwriters listed on Schedule I other than you, the term Representatives as used herein shall mean you, as Underwriters, and the terms Representatives and Underwriters shall mean either the singular or plural as the context requires.

¹ Plus an option to purchase from the Company up to [•] additional Securities solely to cover over-allotments.

As used in this underwriting agreement (this “Agreement”), the “Registration Statement” means the registration statement referred to in paragraph 1(a) hereof, including the exhibits, schedules and financial statements and any prospectus supplement relating to the Securities that is filed with the Securities and Exchange Commission (the “SEC”) pursuant to Rule 424(b) under the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder (the “Securities Act”) and deemed part of such registration statement pursuant to Rule 430A under the Securities Act (“Rule 430A”), as amended at the date and time that this Agreement is executed and delivered by the parties hereto (the “Execution Time”), and, in the event any post-effective amendment thereto or any registration statement and any amendments thereto filed pursuant to Rule 462(b) under the Securities Act (a “Rule 462(b) Registration Statement”) becomes effective prior to the Closing Date (as defined in Section 3 hereof), shall also mean such registration statement as so amended or such Rule 462(b) Registration Statement, as the case may be; the “Effective Date” means each date and time that the Registration Statement, any post-effective amendment or amendments thereto or any Rule 462(b) Registration Statement became or becomes effective; the “Preliminary Prospectus” means any preliminary prospectus referred to in paragraph 1(a) hereof and any preliminary prospectus included in the Registration Statement at the Effective Date that omits information with respect to the Securities and the offering thereof permitted to be omitted from the Registration Statement when it becomes effective pursuant to Rule 430A (the “Rule 430A Information”); and the “Prospectus” means the prospectus relating to the Securities that is first filed pursuant to Rule 424(b) under the Securities Act (“Rule 424(b)”) after the Execution Time.

As used in this Agreement, the “Disclosure Package” shall mean (i) the Preliminary Prospectus that is generally distributed to investors and used to offer the Securities; (ii) any issuer free writing prospectus, as defined in Rule 433 under the Securities Act (an “Issuer Free Writing Prospectus”), identified in Schedule II hereto; and (iii) any other free writing prospectus, as defined in Rule 405 under the Securities Act (a “Free Writing Prospectus”), that the parties hereto shall hereafter expressly agree in writing to treat as part of the Disclosure Package.

1. Representations and Warranties. The Company represents and warrants to, and agrees with, each Underwriter as set forth below in this Section 1.

(a) The Company has prepared and filed with the SEC a registration statement (file number 333-249536) on Form S-1, including a related preliminary prospectus, for the registration of the offering and sale of the Securities under the Securities Act. Such Registration Statement, including any amendments thereto filed prior to the Execution Time, has become effective. The Company may have filed one or more amendments thereto, including a related preliminary prospectus, each of which has previously been furnished to you. The Company will file with the SEC a final prospectus relating to the Securities in accordance with Rule 424(b) after the Execution Time. As filed, such final prospectus shall contain all information required by the Securities Act and the rules thereunder and, except to the extent

the Representatives shall agree in writing to a modification, shall be in all substantive respects in the form furnished to you prior to the Execution Time or, to the extent not completed at the Execution Time, shall contain only such specific additional information and other changes (beyond that contained in the latest Preliminary Prospectus) as the Company has advised you, prior to the Execution Time, will be included or made therein.

(b) On the Effective Date, the Registration Statement did, and when the Prospectus is first filed in accordance with Rule 424(b) and on the Closing Date (as defined herein) and on any date on which Option Securities are purchased, if such date is not the Closing Date (a “settlement date”), the Prospectus (and any supplement thereto) will, comply in all material respects with the applicable requirements of the Securities Act and the rules thereunder; on the Effective Date, at the Execution Time and on the Closing Date, the Registration Statement did not and will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading; and on the date of any filing pursuant to Rule 424(b) and on the Closing Date and any settlement date, the Prospectus (together with any supplement thereto) will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that the Company makes no representations or warranties as to the information contained in or omitted from the Registration Statement or the Prospectus (or any supplement thereto) in reliance upon and in conformity with information furnished in writing to the Company by or on behalf of any Underwriter through the Representatives specifically for inclusion in the Registration Statement or the Prospectus (or any supplement thereto), it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 8 hereof.

(c) (i) The Disclosure Package and the price to the public, the number of Underwritten Securities and the number of Option Securities to be included on the cover page of the Prospectus, when taken together as a whole and (ii) each electronic road show, when taken together as a whole with the Disclosure Package and the price to the public, the number of Underwritten Securities and the number of Option Securities to be included on the cover page of the Prospectus and (iii) any individual Written Testing-the-Waters Communication, when taken together as a whole with the Disclosure Package and the price to the public, the number of Underwritten Securities and the number of Option Securities to be included on the cover page of the Prospectus, does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The preceding sentence does not apply to statements in or omissions from the Disclosure Package based upon and in conformity with written information furnished to the Company by any Underwriter through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the information described as such in Section 8 hereof.

(d) (i) At the time of filing the Registration Statement and (ii) as of the Execution Time (with such date being used as the determination date for purposes of this clause (ii)), the Company was not and is not an Ineligible Issuer (as defined in Rule 405 under the Securities Act (“Rule 405”)), without taking account of any determination by the SEC pursuant to Rule 405 that it is not necessary that the Company be considered an Ineligible Issuer.

(e) From the time of initial confidential submission of the Registration Statement to the SEC (or, if earlier, the first date on which the Company engaged directly or through any Person authorized to act on its behalf in any Testing-the-Waters Communication) through the Execution Time, the Company has been and is an “emerging growth company,” as defined in Section 2(a) of the Securities Act (an “Emerging Growth Company”). “Testing-the-Waters Communication” means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act.

(f) The Company (i) has not alone engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (ii) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule III hereto. “Written Testing-the-Waters Communication” means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405.

(g) Each Issuer Free Writing Prospectus does not include any information that conflicts with the information contained in the Registration Statement, including any document incorporated by reference therein that has not been superseded or modified. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by any Underwriter through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the information described as such in Section 8 hereof.

(h) Each of the Company and its subsidiaries has been duly incorporated and is validly existing as a corporation in good standing under the laws of the jurisdiction in which it is chartered or organized with full corporate power and authority to own or lease, as the case may be, and to operate its properties and conduct its business as described in the Disclosure Package and the Prospectus, and is duly qualified to do business as a foreign corporation and is in good standing under the laws of each jurisdiction which requires such qualification, except when the failure to be qualified or in good standing would not reasonably be expected, individually or in the aggregate, to have a material adverse effect on the condition (financial or otherwise), prospects, earnings, business or properties of the Company and its subsidiaries, taken as a whole, whether or not arising from transactions in the ordinary course of business (a “Material Adverse Effect”).

(i) All the outstanding shares of capital stock of each subsidiary have been duly and validly authorized and issued and are fully paid and non-assessable, and, except as otherwise set forth in the Disclosure Package and the Prospectus, all outstanding shares of capital stock of the subsidiaries are owned by the Company either directly or through wholly owned subsidiaries free and clear of any perfected security interest or any other security interests, claims, liens or encumbrances.

(j) There is no franchise, contract or other document of a character required to be described in the Registration Statement or Prospectus, or to be filed as an exhibit thereto, which is not described or filed as required (and the Preliminary Prospectus contains in all material respects the same description of the foregoing matters contained in the Prospectus); and the statements in the Preliminary Prospectus and the Prospectus under the heading[s] “Tax Matters,” “[•]” and “[•]” insofar as such statements summarize legal matters, agreements, documents or proceedings discussed therein, are accurate and fair summaries of such legal matters, agreements, documents or proceedings.

(k) This Agreement has been duly authorized, executed and delivered by the Company.

(l) The Company is not and, after giving effect to the offering and sale of the Securities and the application of the proceeds thereof as described in the Disclosure Package and the Prospectus, will not be an “investment company” as defined in the Investment Company Act of 1940, as amended.

(m) No consent, approval, authorization, filing with or order of any court or governmental agency or body is required in connection with the transactions contemplated herein, except such as have been obtained under the Securities Act and such as may be required under the listing rules of The Nasdaq Stock Market (“Nasdaq”), the applicable rules of the Financial Industry Regulatory Authority, Inc. (“FINRA”) and the blue sky laws of any jurisdiction in connection with the purchase and distribution of the Securities by the Underwriters in the manner contemplated herein and in the Disclosure Package and the Prospectus.

(n) Neither the issue and sale of the Securities nor the consummation of any other of the transactions herein contemplated nor the fulfillment of the terms hereof will conflict with, result in a breach or violation of, or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, (i) the charter or by-laws of the Company or any of its subsidiaries, (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan

agreement or other agreement, obligation, condition, covenant or instrument to which the Company or any of its subsidiaries is a party or bound or to which its or their property is subject, or (iii) any statute, law, rule, regulation, judgment, order or decree applicable to the Company or any of its subsidiaries of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company or any of its subsidiaries or any of its or their properties.

(o) No holders of securities of the Company have rights to the registration of such securities under the Registration Statement.

(p) The consolidated historical financial statements and schedules of the Company and its consolidated subsidiaries included in the Preliminary Prospectus, the Prospectus and the Registration Statement present fairly in all material respects the financial condition, results of operations and cash flows of the Company as of the dates and for the periods indicated, comply as to form in all material respects with the applicable accounting requirements of the Securities Act and have been prepared in conformity with generally accepted accounting principles applied on a consistent basis throughout the periods involved (except as otherwise noted therein). The selected financial data set forth under the caption "Selected Financial Information" in the Preliminary Prospectus, the Prospectus and Registration Statement fairly present in all material respects, on the basis stated in the Preliminary Prospectus, the Prospectus and the Registration Statement, the information included therein.

(q) No action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries or its or their property is pending or, to the knowledge of the Company, threatened that (i) could reasonably be expected to have a material adverse effect on the performance of this Agreement or the consummation of any of the transactions contemplated hereby or (ii) could reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(r) Each of the Company and each of its subsidiaries owns or leases all such properties as are necessary to the conduct of its operations as presently conducted, except as would reasonably be expected to have a Material Adverse Effect.

(s) Neither the Company nor any subsidiary is in violation or default of (i) any provision of its charter or bylaws, (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan agreement or other agreement, obligation, condition, covenant or instrument to which it is a party or bound or to which its property is subject, or (iii) any statute, law, rule, regulation, judgment, order or decree of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company or such subsidiary or any of its properties, as applicable, except in the case of clauses (ii) and (iii) for any such violation or default as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(t) CohnReznick LLP, who have certified certain financial statements of the Company and its consolidated subsidiaries and delivered their report with respect to the audited consolidated financial statements and schedules included in the Disclosure Package and the Prospectus, are independent public accountants with respect to the Company within the meaning of the Securities Act and the applicable published rules and regulations thereunder.

(u) There are no transfer taxes or other similar fees or charges under Federal law or the laws of any state, or any political subdivision thereof, required to be paid in connection with the execution and delivery of this Agreement or the issuance by the Company or sale by the Company of the Securities.

(v) The Company has filed all tax returns that are required to be filed or has requested extensions thereof (except in any case in which the failure so to file would not have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto)) and has paid all taxes required to be paid by it and any other assessment, fine or penalty levied against it, to the extent that any of the foregoing is due and payable, except for any such assessment, fine or penalty that is currently being contested in good faith or as would not have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(w) No labor problem or dispute with the employees of the Company or any of its subsidiaries exists or is threatened or imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its or its subsidiaries' principal suppliers, contractors or customers, that could have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(x) The Company and each of its subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as the Company reasonably believes are prudent and customary in the businesses in which they are engaged; all policies of insurance insuring the Company or any of its subsidiaries or their respective businesses, assets, employees, officers and directors are in full force and effect; the Company and its subsidiaries are in compliance with the terms of such policies and instruments in all material respects; and there are no material claims by the Company or any of its subsidiaries under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; neither the Company nor any such subsidiary has been refused any insurance coverage sought or applied for; and neither the Company nor any such subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(y) No subsidiary of the Company is currently prohibited, directly or indirectly, from paying any dividends to the Company, from making any other distribution on such subsidiary's capital stock, from repaying to the Company any loans or advances to such subsidiary from the Company or from transferring any of such subsidiary's property or assets to the Company or any other subsidiary of the Company, except as described in or contemplated by the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(z) The Company and its subsidiaries possess all licenses, certificates, permits and other authorizations issued by all applicable authorities ("Regulatory Permits") necessary to conduct their respective businesses, and neither the Company nor any such subsidiary has received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(aa) The Company and each of its subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (v) the interactive data in XBRL included or incorporated by reference in the Registration Statement, the Preliminary Prospectus and the Prospectus is in compliance with the SEC's published rules, regulations and guidelines applicable thereto. The Company and its subsidiaries' internal controls over financial reporting are effective and the Company and its subsidiaries are not aware of any material weakness in their internal controls over financial reporting.

(bb) The Company and its subsidiaries maintain "disclosure controls and procedures" (as such term is defined in Rule 13a-15(e) under the Securities and Exchange Act 1934, as amended, and the rules and regulations promulgated thereunder (the "Exchange Act")); such disclosure controls and procedures are effective.

(cc) The Company has not taken, directly or indirectly (without giving effect to the activities of the Underwriters), any action designed to or that would constitute or that might reasonably be expected to cause or result in, under the Exchange Act or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(dd) The Company and its subsidiaries are (i) in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants (“Environmental Laws”), (ii) have received and are in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses and (iii) have not received notice of any actual or potential liability under any environmental law, except where such non-compliance with Environmental Laws, failure to receive required permits, licenses or other approvals, or liability as would not reasonably be expected, individually or in the aggregate, have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto). Except as set forth in the Disclosure Package and the Prospectus, neither the Company nor any of the subsidiaries has been named as a “potentially responsible party” under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

(ee) In the ordinary course of its business, the Company periodically reviews the effect of Environmental Laws on the business, operations and properties of the Company and its subsidiaries, in the course of which it identifies and evaluates associated costs and liabilities (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws, or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties). On the basis of such review, the Company has reasonably concluded that such associated costs and liabilities would not, singly or in the aggregate, have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(ff) To the Company’s knowledge, the research, studies and clinical trials conducted by or on behalf of the Company or being relied on by the Company have been and, if still pending, are being conducted, in all material respects, in accordance with experimental protocols and procedures pursuant to all applicable laws and Regulatory Permits and the results of such research, studies and clinical trials described in the Disclosure Package and the Prospectus, are accurate and fairly present, in all material respects, the data derived from such research, studies, and clinical trials; any research, studies and clinical trials conducted by or on behalf of the Company if still pending, are, to the Company’s knowledge, being conducted in all material respects in accordance with professional and scientific standards and the applicable requirements of the United States Food and Drug Administration (the “FDA”) or other federal, state, local or foreign agencies or bodies engaged in the regulation of pharmaceuticals and biological products such as those being developed by the Company (collectively, “Governmental Authorities”); the Company has not received any notice or correspondence from the FDA nor any Governmental Authority requiring the termination, suspension or modification of any such study or clinical trial; and except to the extent disclosed in the Disclosure Package and the Prospectus, the Company is not aware of any research, study or clinical trial, the results of which the Company believes reasonably call into question the results described or referred to in the Disclosure Package and the Prospectus.

(gg) None of the following events has occurred or exists: (i) a failure to fulfill the obligations, if any, under the minimum funding standards of Section 302 of the United States Employee Retirement Income Security Act of 1974, as amended (“ERISA”), and the regulations and published interpretations thereunder with respect to a Plan, determined without regard to any waiver of such obligations or extension of any amortization period, that would reasonably be expected to have a Material Adverse Effect; (ii) an audit or investigation by the Internal Revenue Service, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other federal or state governmental agency or any foreign regulatory agency with respect to the employment or compensation of employees by any of the Company or any of its subsidiaries that would reasonably be expected to have a Material Adverse Effect; (iii) any breach of any contractual obligation, or any violation of law or applicable qualification standards, with respect to the employment or compensation of employees by the Company or any of its subsidiaries that would reasonably be expected to have a Material Adverse Effect. None of the following events has occurred or is reasonably likely to occur: (i) a material increase in the aggregate amount of contributions required to be made to all Plans in the current fiscal year of the Company and its subsidiaries compared to the amount of such contributions made in the most recently completed fiscal year of the Company and its subsidiaries, other than increases in the ordinary course resulting from an increase in the number of eligible participants in such Plans or increases resulting from increased participation by eligible participants in such Plans; (ii) a material increase in the “accumulated post-retirement benefit obligations” (within the meaning of Statement of Financial Accounting Standards 106) of the Company and its subsidiaries compared to the amount of such obligations in the most recently completed fiscal year of the Company and its subsidiaries; (iii) any event or condition giving rise to a liability under Title IV of ERISA that would reasonably be expected to have a Material Adverse Effect; or (iv) the filing of a claim by one or more employees or former employees of the Company or any of its subsidiaries related to their employment that could have a Material Adverse Effect. For purposes of this paragraph, the term “Plan” means a plan (within the meaning of Section 3(3) of ERISA) subject to Title IV of ERISA with respect to which the Company or any of its subsidiaries may have any liability.

(hh) There is and has been no failure on the part of the Company and any of the Company’s directors or officers, in their capacities as such, to comply with any provision of the Sarbanes-Oxley Act of 2002, as amended, and the rules and regulations promulgated in connection thereunder (the “Sarbanes-Oxley Act”), including Section 402 relating to loans and Sections 302 and 906 relating to certifications.

(ii) Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries is aware of or has taken any action, directly or indirectly, that could result in a violation or a sanction for violation by such

persons of the Foreign Corrupt Practices Act of 1977 or the U.K. Bribery Act 2010, each as may be amended, or similar law of any other relevant jurisdiction, or the rules or regulations thereunder; and the Company and its subsidiaries have instituted and maintain policies and procedures to ensure compliance therewith. No part of the proceeds of the offering will be used, directly or indirectly, in violation of the Foreign Corrupt Practices Act of 1977 or the U.K. Bribery Act 2010, each as may be amended, or similar law of any other relevant jurisdiction, or the rules or regulations thereunder.

(jj) The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements and the money laundering statutes and the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the “Money Laundering Laws”) and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

(kk) Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company or any of its subsidiaries (i) is, or is controlled or 50% or more owned in the aggregate by or is acting on behalf of, one or more individuals or entities that are currently the subject of any sanctions administered or enforced by the United States (including any administered or enforced by the Office of Foreign Assets Control of the U.S. Department of the Treasury, the U.S. Department of State or the Bureau of Industry and Security of the U.S. Department of Commerce), the United Nations Security Council, the European Union, a member state of the European Union (including sanctions administered or enforced by Her Majesty’s Treasury of the United Kingdom), the Swiss Secretariat of Economic Affairs or other relevant sanctions authority (collectively, “Sanctions” and such persons, “Sanctioned Persons” and each such person, a “Sanctioned Person”), (ii) is located, organized or resident in a country or territory that is, or whose government is, the subject of Sanctions that broadly prohibit dealings with that country or territory (collectively, “Sanctioned Countries” and each, a “Sanctioned Country”) or (iii) will, directly or indirectly, use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other individual or entity in any manner that would result in a violation of any Sanctions by, or could result in the imposition of Sanctions against, any individual or entity (including any individual or entity participating in the offering, whether as underwriter, advisor, investor or otherwise).

(ll) Neither the Company nor any of its subsidiaries has engaged in any dealings or transactions with or for the benefit of a Sanctioned Person, or with or in a Sanctioned Country, in the preceding 3 years, nor does the Company or any of its subsidiaries have any plans to engage in dealings or transactions with or for the benefit of a Sanctioned Person, or with or in a Sanctioned Country.

(mm) The subsidiaries listed on Annex A attached hereto are the only significant subsidiaries of the Company as defined by Rule 1-02 of Regulation S-X.

(nn) The Company and its subsidiaries own, possess, license or have other rights to use, on reasonable terms, all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, technology, know-how and other intellectual property (collectively, the “**Intellectual Property**”) necessary for the conduct of the Company’s business as now conducted or as proposed in the Disclosure Package and Prospectus to be conducted. Except as set forth in the Disclosure Package and the Prospectus under the caption “**Business—Intellectual Property**” (a) there are no rights of third parties to any such Intellectual Property; (b) there is no material infringement by third parties of any such Intellectual Property; (c) there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the Company’s rights in or to any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (d) there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (e) there is no pending or threatened action, suit, proceeding or claim by others that the Company infringes or otherwise violates any patent, trademark, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any other fact which would form a reasonable basis for any such claim; (f) there is no U.S. patent or published U.S. patent application which contains claims that dominate or may dominate any Intellectual Property described in the Disclosure Package and the Prospectus as being owned by or licensed to the Company or that interferes with the issued or pending claims of any such Intellectual Property; and (g) there is no prior art of which the Company is aware that may render any U.S. patent held by the Company invalid or any U.S. patent application held by the Company un-patentable which has not been disclosed to the U.S. Patent and Trademark Office.

(oo) The statements contained in the Preliminary Prospectus and the Prospectus under the captions “**Risk Factors — Risks Related to our Intellectual Property**” and “**Business — Intellectual Property,**” insofar as such statements summarize legal matters, agreements, documents, or proceedings discussed therein, are accurate and fair summaries of such legal matters, agreements, documents or proceedings in all material respects.

(pp) Except as disclosed in the Registration Statement, the Disclosure Package and the Prospectus, the Company (i) does not have any material lending or other relationship with any bank or lending affiliate of the Representatives and (ii) does not intend to use any of the proceeds from the sale of the Securities hereunder to repay any outstanding debt owed to any affiliate of the Representatives.

(qq) Neither the Company nor any of its subsidiaries nor any of its or their properties or assets has any immunity from the jurisdiction of any court or from any legal process (whether through service or notice, attachment prior to judgment, attachment in aid of execution or otherwise) under the laws of the State of Delaware.

Any certificate signed by any officer of the Company and delivered to the Representatives or counsel for the Underwriters in connection with the offering of the Securities shall be deemed a representation and warranty by the Company, as to matters covered thereby, to each Underwriter.

2. Purchase and Sale.

(a) Subject to the terms and conditions and in reliance upon the representations and warranties herein set forth, the Company agrees to sell to each Underwriter, and each Underwriter agrees, severally and not jointly, to purchase from the Company, at a purchase price of \$[•] per share, the amount of the Underwritten Securities set forth opposite such Underwriter's name in Schedule I hereto.

(b) Subject to the terms and conditions and in reliance upon the representations and warranties herein set forth, the Company hereby grants an option to the several Underwriters to purchase, severally and not jointly, up to [•] Option Securities at the same purchase price per share as the Underwriters shall pay for the Underwritten Securities, less an amount per share equal to any dividends or distributions declared by the Company and payable on the Underwritten Securities but not payable on the Option Securities. Said option may be exercised only to cover over-allotments in the sale of the Underwritten Securities by the Underwriters. Said option may be exercised in whole or in part at any time on or before the 30th day after the date of the Prospectus upon written or telegraphic notice by the Representatives to the Company setting forth the number of shares of the Option Securities as to which the several Underwriters are exercising the option and the settlement date. The number of Option Securities to be purchased by each Underwriter shall be the same percentage of the total number of shares of the Option Securities to be purchased by the several Underwriters as such Underwriter is purchasing of the Underwritten Securities, subject to such adjustments as you in your absolute discretion shall make to eliminate any fractional shares.

3. Delivery and Payment. Delivery of and payment for the Underwritten Securities and the Option Securities (if the option provided for in Section 2(b) hereof shall have been exercised on or before the third Business Day immediately preceding the Closing Date) shall be made at 10:00 AM, New York City time, on [•], 2020, or at such time on such later date not more than three Business Days after the foregoing date as the Representatives shall designate, which date and time may be postponed by agreement between the Representatives and the Company or as provided in Section 9 hereof (such date and time of delivery and payment for the Securities being herein called the "Closing Date"). As used herein, "Business Day" shall mean any day other than a Saturday, a Sunday or a legal holiday or a day on which banking institutions or trust companies are authorized or obligated by law to close in New York City.

Delivery of the Securities shall be made to the Representatives for the respective accounts of the several Underwriters against payment by the several Underwriters through the Representatives of the purchase price thereof to or upon the order of the Company by wire transfer payable in same-day funds to an account specified by the Company. Delivery of the Underwritten Securities and the Option Securities shall be made through the facilities of The Depository Trust Company unless the Representatives shall otherwise instruct.

If the option provided for in Section 2(b) hereof is exercised after the third Business Day immediately preceding the Closing Date, the Company will deliver the Option Securities (at the expense of the Company) to the Representatives, at 388 Greenwich Street, New York, New York, on the date specified by the Representatives (which shall be within three Business Days after exercise of said option) for the respective accounts of the several Underwriters, against payment by the several Underwriters through the Representatives of the purchase price thereof to or upon the order of the Company by wire transfer payable in same-day funds to an account specified by the Company. If settlement for the Option Securities occurs after the Closing Date, the Company will deliver to the Representatives on the settlement date for the Option Securities, and the obligation of the Underwriters to purchase the Option Securities shall be conditioned upon receipt of, supplemental opinions, certificates and letters confirming as of such date the opinions, certificates and letters delivered on the Closing Date pursuant to Section 6 hereof.

4. Offering by Underwriters. It is understood that the several Underwriters propose to offer the Securities for sale to the public as set forth in the Prospectus.

5. Agreements. The Company agrees with the several Underwriters that:

(a) Prior to the termination of the offering of the Securities, the Company will not file any amendment of the Registration Statement or supplement to the Prospectus or any Rule 462(b) Registration Statement unless the Company has furnished you a copy for your review prior to filing and will not file any such proposed amendment or supplement to which you reasonably object. The Company will cause the Prospectus, properly completed, and any supplement thereto to be filed in a form approved by the Representatives with the SEC pursuant to the applicable paragraph of Rule 424(b) within the time period prescribed and will provide evidence satisfactory to the Representatives of such timely filing. The Company will promptly advise the Representatives (i) when the Prospectus, and any supplement thereto, shall have been filed (if required) with the SEC pursuant to Rule 424(b) or when any Rule 462(b) Registration Statement shall have been filed with the SEC, (ii) when, prior to termination of the offering of the Securities, any amendment to the Registration Statement shall have been filed or become effective, (iii) of any request by the SEC or its staff for any amendment of the Registration Statement, or any Rule 462(b) Registration Statement, or for any supplement to the Prospectus or for any additional information, (iv) of the issuance by the SEC of any stop order suspending the effectiveness of the Registration Statement or of any notice objecting to its use or the institution or threatening of any proceeding for that purpose and (v) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Securities for sale in any jurisdiction or the institution or threatening

of any proceeding for such purpose. The Company will use its best efforts to prevent the issuance of any such stop order or the occurrence of any such suspension or objection to the use of the Registration Statement and, upon such issuance, occurrence or notice of objection, to obtain as soon as possible the withdrawal of such stop order or relief from such occurrence or objection, including, if necessary, by filing an amendment to the Registration Statement or a new registration statement and using its best efforts to have such amendment or new registration statement declared effective as soon as practicable.

(b) If, at any time prior to the filing of the Prospectus pursuant to Rule 424(b), any event occurs as a result of which the Disclosure Package would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, the Company will (i) notify promptly the Representatives so that any use of the Disclosure Package may cease until it is amended or supplemented; (ii) amend or supplement the Disclosure Package to correct such statement or omission; and (iii) supply any amendment or supplement to you in such quantities as you may reasonably request.

(c) If, at any time when a prospectus relating to the Securities is required to be delivered under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act ("Rule 172")), any event occurs as a result of which the Prospectus as then supplemented would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, or if it shall be necessary to amend the Registration Statement or supplement the Prospectus to comply with the Securities Act or the rules thereunder, the Company promptly will (i) notify the Representatives of any such event; (ii) prepare and file with the SEC, subject to the second sentence of paragraph (a) of this Section 5, an amendment or supplement which will correct such statement or omission or effect such compliance; and (iii) supply any supplemented Prospectus to you in such quantities as you may reasonably request.

(d) As soon as practicable, the Company will make generally available to its security holders and to the Representatives an earnings statement or statements of the Company and its subsidiaries which will satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 under the Securities Act.

(e) The Company will furnish to the Representatives and counsel for the Underwriters, without charge, signed copies of the Registration Statement (including exhibits thereto) and to each other Underwriter a copy of the Registration Statement (without exhibits thereto) and, so long as delivery of a prospectus by an Underwriter or dealer may be required by the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172), as many copies of each Preliminary Prospectus, the Prospectus and each Issuer Free Writing Prospectus and any supplement thereto as the Representatives may reasonably request. The Company will pay the expenses of printing or other production of all documents relating to the offering.

(f) The Company will arrange, if necessary, for the qualification of the Securities for sale under the laws of such jurisdictions as the Representatives may reasonably designate and will maintain such qualifications in effect so long as required for the distribution of the Securities; provided that in no event shall the Company be obligated to qualify to do business in any jurisdiction where it is not now so qualified or to take any action that would subject it to service of process in suits, other than those arising out of the offering or sale of the Securities, in any jurisdiction where it is not now so subject.

(g) The Company will not, without the prior written consent of the Representatives, offer, sell, contract to sell, pledge, or otherwise dispose of, (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise) by the Company or any affiliate of the Company or any person in privity with the Company or any affiliate of the Company) directly or indirectly, including the filing (or participation in the filing) of a registration statement with the SEC in respect of, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Exchange Act, any other shares of Common Stock or any securities convertible into, or exercisable, or exchangeable for, shares of Common Stock; or publicly announce an intention to effect any such transaction, for a period of 180 days after the date of this Agreement, provided, however, that the Company may: (i) effect the transactions contemplated hereby; (ii) grant options or issue shares of Common Stock to its employees, officers, directors, advisors or consultants pursuant to employee benefit plans in effect on the date hereof and as described in the Registration Statement, the Disclosure Package and the Prospectus, provided, that each recipient of such securities pursuant to this clause (ii) agrees to restrictions on the resale of securities that are consistent with the provisions set forth in the lock-up letter described in Section 5(g) hereof; (iii) file one or more registration statements on Form S-8 relating to stock options or employee benefit plans of the Company described in the Registration Statement, the Disclosure Package and Prospectus; (iv) file one or more registration statements on Form S-1 or Form S-3, as applicable, and amendments thereto, relating to registration rights granted under the Registration Rights Agreement, dated June 19, 2020, by and among Company and the parties thereto, or (v) offer, issue and sell Common Stock or securities convertible into or exercisable or exchangeable for Common Stock in connection with any bona fide (1) mergers, (2) acquisition of securities, businesses, property or other assets, (3) joint ventures, (4) strategic alliances, (5) partnerships with experts or other talent to develop or provide content, (6) equipment leasing arrangements or (7) commercial or venture debt lending arrangements, provided, that the aggregate number of Common Stock or securities convertible into or exercisable for Common Stock (on an as-converted or as-exercised basis, as the case may be) that the Company may issue or agree to issue pursuant to this clause (iv) shall not exceed 5% of the total number of shares of Common Stock issued and outstanding immediately following the completion of the transactions contemplated by this Agreement, and provided, further, that each recipient of such securities agrees to restrictions on the resale of securities that are consistent with the provisions set forth in the lock-up letter described in Section 5(g) hereof.

(h) If the Representatives, in their sole discretion, agree to release or waive the restrictions set forth in a lock-up letter described in Section 6(i) hereof for an officer or director of the Company and provides the Company with notice of the impending release or waiver at least three Business Days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit B hereto through a major news service at least two Business Days before the effective date of the release or waiver.

(i) The Company will not take, directly or indirectly (without giving effect to activities by the Underwriters), any action designed to or that would constitute or that might reasonably be expected to cause or result in, under the Exchange Act or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(j) The Company agrees to pay the costs and expenses relating to the following matters: (i) the preparation, printing or reproduction and filing with the SEC of the Registration Statement (including financial statements and exhibits thereto), each Preliminary Prospectus, the Prospectus and each Issuer Free Writing Prospectus, and each amendment or supplement to any of them; (ii) the printing (or reproduction) and delivery (including postage, air freight charges and charges for counting and packaging) of such copies of the Registration Statement, each Preliminary Prospectus, the Prospectus and each Issuer Free Writing Prospectus, and all amendments or supplements to any of them, as may, in each case, be reasonably requested for use in connection with the offering and sale of the Securities; (iii) the preparation, printing, authentication, issuance and delivery of certificates for the Securities, including any stamp or transfer taxes in connection with the original issuance and sale of the Securities; (iv) the printing (or reproduction) and delivery of this Agreement, any blue sky memorandum and all other agreements or documents printed (or reproduced) and delivered in connection with the offering of the Securities; (v) the registration of the Securities under the Exchange Act and the listing of the Securities on the Nasdaq Capital Market; (vi) any registration or qualification of the Securities for offer and sale under the securities or blue sky laws of the several states (including filing fees and the reasonable fees and expenses of counsel for the Underwriters relating to such registration and qualification); (vii) any filings required to be made with the Financial Industry Regulatory Authority, Inc. ("FINRA") (including filing fees and the reasonable fees and expenses of counsel for the Underwriters relating to such filings); (viii) the transportation and other expenses incurred by or on behalf of Company representatives in connection with presentations to prospective purchasers of the Securities; (ix) the fees and expenses of the Company's accountants and the fees and expenses of counsel (including local and special counsel) for the Company; and (x) all other costs and expenses incident to the performance by the Company of its obligations hereunder; provided, however, that the reasonable fees and expenses of counsel for the Underwriters incurred pursuant to clauses (vi) and (vii) of this Section 5(j) shall not exceed \$40,000 in the aggregate.

(k) The Company agrees that, unless it has or shall have obtained the prior written consent of the Representatives, and each Underwriter, severally and not jointly, agrees with the Company that, unless it has or shall have obtained, as the case may be, the prior written consent of the Company, it has not made and will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a Free Writing Prospectus required to be filed by the Company with the SEC or retained by the Company under Rule 433 under the Securities Act ("Rule 433"); provided that the prior written consent of the parties hereto shall be deemed to have been given in respect of the Free Writing Prospectuses included in Schedule II hereto and any electronic road show. Any such free writing prospectus consented to by the Representatives or the Company is hereinafter referred to as a "Permitted Free Writing Prospectus." The Company agrees that (x) it has treated and will treat, as the case may be, each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus and (y) it has complied and will comply, as the case may be, with the requirements of Rule 164 under the Securities Act ("Rule 164") and Rule 433 applicable to any Permitted Free Writing Prospectus, including in respect of timely filing with the SEC, legending and record keeping.

(l) The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (a) completion of the distribution of the Securities within the meaning of the Securities Act and (b) completion of the 180-day restricted period referred to in Section 5(g) hereof.

(m) If at any time following the distribution of any Written Testing-the-Waters Communication, any event occurs as a result of which such Written Testing-the-Waters Communication would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, the Company will (i) notify promptly the Representatives so that use of the Written Testing-the-Waters Communication may cease until it is amended or supplemented; (ii) amend or supplement the Written Testing-the-Waters Communication to correct such statement or omission; and (iii) supply any amendment or supplement to the Representatives in such quantities as may be reasonably requested.

6. Conditions to the Obligations of the Underwriters. The obligations of the Underwriters to purchase the Underwritten Securities and the Option Securities, as the case may be, shall be subject to the accuracy of the representations and warranties on the part of the Company contained herein as of the Execution Time, the Closing Date and any settlement date pursuant to Section 3 hereof, to the accuracy of the statements of the Company made in any certificates pursuant to the provisions hereof, to the performance by the Company of its obligations hereunder and to the following additional conditions:

(a) The Prospectus, and any supplement thereto, have been filed in the manner and within the time period required by Rule 424(b); any material required to be filed by the Company pursuant to Rule 433(d) shall have been filed with the SEC within the applicable time periods prescribed for such filings by Rule 433; and no stop order suspending the effectiveness of the Registration Statement or any notice objecting to its use shall have been issued and no proceedings for that purpose shall have been instituted or threatened.

(b) The Company shall have requested and caused Goodwin Procter LLP, counsel for the Company, to have furnished to the Representatives their opinion, dated the Closing Date and addressed to the Representatives, in a form reasonably acceptable to the Representatives.

(c) The Representatives shall have received from DT Ward, PC, intellectual property counsel for the Underwriters, such opinion or opinions, dated the Closing Date and addressed to the Representatives, with respect to the Company's intellectual property and other related matters as the Representatives may reasonably require, and the Company shall have furnished to such counsel such documents as they request for the purpose of enabling them to pass upon such matters.

(d) The Representatives shall have received from Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., counsel for the Underwriters, such opinion or opinions, dated the Closing Date and addressed to the Representatives, with respect to the issuance and sale of the Securities, the Registration Statement, the Disclosure Package, the Prospectus (together with any supplement thereto) and other related matters as the Representatives may reasonably require, and the Company shall have furnished to such counsel such documents as they request for the purpose of enabling them to pass upon such matters.

(e) The Company shall have furnished to the Representatives a certificate of the Company, signed by the Chief Executive Officer or the President and the principal financial or accounting officer of the Company, dated the Closing Date, to the effect that the signers of such certificate have carefully examined the Registration Statement, the Disclosure Package, the Prospectus and any amendment or supplement thereto, as well as each electronic road show used in connection with the offering of the Securities, and this Agreement and that:

(i) the representations and warranties of the Company in this Agreement are true and correct on and as of the Closing Date with the same effect as if made on the Closing Date and the Company has complied with all the agreements and satisfied all the conditions on its part to be performed or satisfied at or prior to the Closing Date;

(ii) no stop order suspending the effectiveness of the Registration Statement or any notice objecting to its use has been issued and no proceedings for that purpose have been instituted or, to the Company's knowledge, threatened; and

(iii) since the date of the most recent financial statements included in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto), there has been no Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(f) The Company shall have requested and caused CohnReznick LLP to have furnished to the Representatives, at the Execution Time and at the Closing Date, letters, dated respectively as of the Execution Time and as of the Closing Date, in form and substance satisfactory to the Representatives, containing statements and information of the type ordinarily included in accountants "comfort letters" to underwriters.

(g) Subsequent to the Execution Time or, if earlier, the dates as of which information is given in the Registration Statement (exclusive of any amendment thereof) and the Prospectus (exclusive of supplement thereto), there shall not have been (i) any change or decrease specified in the letter or letters referred to in paragraph (e) of this Section 6 or (ii) any change, or any development involving a prospective change, in or affecting the condition (financial or otherwise), earnings, business or properties of the Company and its subsidiaries taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto) the effect of which, in any case referred to in clause (i) or (ii) above, is, in the sole judgment of the Representatives, so material and adverse as to make it impractical or inadvisable to proceed with the offering or delivery of the Securities as contemplated by the Registration Statement (exclusive of any amendment thereof), the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(h) Prior to the Closing Date, the Company shall have furnished to the Representatives such further information, certificates and documents as the Representatives may reasonably request.

(i) The Securities shall have been listed and admitted and authorized for trading on the Nasdaq Capital Market, and satisfactory evidence of such actions shall have been provided to the Representatives.

(j) At the Execution Time, the Company shall have furnished to the Representatives a letter substantially in the form of Exhibit A hereto from each officer and director and certain equityholders of the Company addressed to the Representatives.

If any of the conditions specified in this Section 6 shall not have been fulfilled when and as provided in this Agreement, or if any of the opinions and certificates mentioned above or elsewhere in this Agreement shall not be reasonably satisfactory in form and substance to the Representatives and counsel for the Underwriters, this Agreement and all obligations of the Underwriters hereunder may be canceled at, or at any time prior to, the Closing Date by the Representatives. Notice of such cancellation shall be given to the Company in writing or by telephone or facsimile confirmed in writing.

The documents required to be delivered by this Section 6 shall be delivered at the office of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., counsel for the Underwriters, at 666 3rd Ave, New York, NY 10017, on the Closing Date.

7. Reimbursement of Underwriters' Expenses. If the sale of the Securities provided for herein is not consummated because any condition to the obligations of the Underwriters set forth in Section 6 hereof is not satisfied, because of any termination pursuant to Section 10 hereof or because of any refusal, inability or failure on the part of the Company to perform any agreement herein or comply with any provision hereof other than by reason of a default by any of the Underwriters, the Company will reimburse the Underwriters severally through Citigroup Global Markets Inc. on demand for all expenses (including reasonable fees and disbursements of counsel) that shall have been incurred by them in connection with the proposed purchase and sale of the Securities.

8. Indemnification and Contribution.

(a) The Company agrees to indemnify and hold harmless each Underwriter, the directors, officers, employees, affiliates and agents of each Underwriter and each person who controls any Underwriter within the meaning of either the Securities Act or the Exchange Act against any and all losses, claims, damages or liabilities, joint or several, to which they or any of them may become subject under the Securities Act, the Exchange Act or other Federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in the registration statement for the registration of the Securities as originally filed or in any amendment thereof, or in any Preliminary Prospectus, or the Prospectus, any Issuer Free Writing Prospectus, or any Written Testing-the-Waters Communication or in any amendment thereof or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, and agrees to reimburse each such indemnified party, as incurred, for any legal or other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon and in conformity with written information furnished to the Company by or on behalf of any Underwriter through the Representatives specifically for inclusion therein. This indemnity agreement will be in addition to any liability which the Company may otherwise have.

(b) Each Underwriter severally and not jointly agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signs the Registration Statement, and each person who controls the Company within the meaning of either the Securities Act or the Exchange Act, to the same extent as the foregoing indemnity from the Company to each Underwriter, but only with reference to written information relating to such Underwriter furnished to the Company by or on behalf of such Underwriter through the Representatives specifically for inclusion in the documents referred to in the foregoing indemnity. This indemnity agreement will be in addition to any liability which any Underwriter may otherwise have. The Company acknowledges that the statements set forth (i) in the last paragraph of the cover page regarding delivery of the Securities and, under the heading "Underwriting," (ii) the list of Underwriters and their respective participation in the sale of the Securities, (iii) the sentences related to concessions and reallowances and (iv) the paragraph related to stabilization, syndicate covering transactions and penalty bids in the Preliminary Prospectus and the Prospectus constitute the only information furnished in writing by or on behalf of the several Underwriters for inclusion in the Preliminary Prospectus, the Prospectus or any Issuer Free Writing Prospectus.

(c) Promptly after receipt by an indemnified party under this Section 8 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against the indemnifying party under this Section 8, notify the indemnifying party in writing of the commencement thereof; but the failure so to notify the indemnifying party (i) will not relieve it from liability under paragraph (a) or (b) above unless and to the extent it did not otherwise learn of such action and such failure results in the forfeiture by the indemnifying party of substantial rights and defenses and (ii) will not, in any event, relieve the indemnifying party from any obligations to any indemnified party other than the indemnification obligation provided in paragraph (a) or (b) above. The indemnifying party shall be entitled to appoint counsel of the indemnifying party's choice at the indemnifying party's expense to represent the indemnified party in any action for which indemnification is sought (in which case the indemnifying party shall not thereafter be responsible for the fees and expenses of any separate counsel retained by the indemnified party or parties except as set forth below); provided, however, that such counsel shall be satisfactory to the indemnified party. Notwithstanding the indemnifying party's election to appoint counsel to represent the indemnified party in an action, the indemnified party shall have the right to employ separate counsel (including local counsel), and the indemnifying party shall bear the reasonable fees, costs and expenses of such separate counsel (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel, in addition to local counsel) if (i) the use of counsel chosen by the indemnifying party to represent the indemnified party would present such counsel with a conflict of interest, (ii) the actual or potential defendants in, or targets of, any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, (iii) the indemnifying party shall not have employed counsel

satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of the institution of such action or (iv) the indemnifying party shall authorize the indemnified party to employ separate counsel at the expense of the indemnifying party. An indemnifying party will not, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any pending or threatened claim, action, suit or proceeding in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified parties are actual or potential parties to such claim or action) unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising out of such claim, action, suit or proceeding and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act, by or on behalf of any indemnified party.

(d) In the event that the indemnity provided in paragraph (a), (b) or (c) of this Section 8 is unavailable to or insufficient to hold harmless an indemnified party for any reason, the Company and the Underwriters severally agree to contribute to the aggregate losses, claims, damages and liabilities (including legal or other expenses reasonably incurred in connection with investigating or defending the same) (collectively, "Losses") to which the Company and one or more of the Underwriters may be subject in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and by the Underwriters on the other from the offering of the Securities. If the allocation provided by the immediately preceding sentence is unavailable for any reason, the Company and the Underwriters severally shall contribute in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company on the one hand and of the Underwriters on the other in connection with the statements or omissions which resulted in such Losses as well as any other relevant equitable considerations. Benefits received by the Company shall be deemed to be equal to the total net proceeds from the offering (before deducting expenses) received by it, and benefits received by the Underwriters shall be deemed to be equal to the total underwriting discounts and commissions, in each case as set forth on the cover page of the Prospectus. Relative fault shall be determined by reference to, among other things, whether any untrue or any alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information provided by the Company on the one hand or the Underwriters on the other, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contribution were determined by pro rata allocation or any other method of allocation which does not take account of the equitable considerations referred to above. Notwithstanding the provisions of this paragraph (e), in no event shall an Underwriter be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the offering of the Securities exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. Notwithstanding the provisions of this paragraph (e), no person guilty of fraudulent

misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 8, each person who controls an Underwriter within the meaning of either the Securities Act or the Exchange Act and each director, officer, employee, affiliate and agent of an Underwriter shall have the same rights to contribution as such Underwriter, and each person who controls the Company within the meaning of either the Securities Act or the Exchange Act, each officer of the Company who shall have signed the Registration Statement and each director of the Company shall have the same rights to contribution as the Company, subject in each case to the applicable terms and conditions of this paragraph (e).

9. Default by an Underwriter. If any one or more Underwriters shall fail to purchase and pay for any of the Securities agreed to be purchased by such Underwriter or Underwriters hereunder and such failure to purchase shall constitute a default in the performance of its or their obligations under this Agreement, the remaining Underwriters shall be obligated severally to take up and pay for (in the respective proportions which the amount of Securities set forth opposite their names in Schedule I hereto bears to the aggregate amount of Securities set forth opposite the names of all the remaining Underwriters) the Securities which the defaulting Underwriter or Underwriters agreed but failed to purchase; provided, however, that in the event that the aggregate amount of Securities which the defaulting Underwriter or Underwriters agreed but failed to purchase shall exceed 10% of the aggregate amount of Securities set forth in Schedule I hereto, the remaining Underwriters shall have the right to purchase all, but shall not be under any obligation to purchase any, of the Securities, and if such non-defaulting Underwriters do not purchase all the Securities, this Agreement will terminate without liability to any non-defaulting Underwriter or the Company. In the event of a default by any Underwriter as set forth in this Section 9, the Closing Date shall be postponed for such period, not exceeding five Business Days, as the Representatives shall determine in order that the required changes in the Registration Statement and the Prospectus or in any other documents or arrangements may be effected. Nothing contained in this Agreement shall relieve any defaulting Underwriter of its liability, if any, to the Company and any non-defaulting Underwriter for damages occasioned by its default hereunder.

10. Termination. This Agreement shall be subject to termination in the absolute discretion of the Representatives, by notice given to the Company prior to delivery of and payment for the Securities, if at any time prior to such delivery and payment (i) trading in the Company's Common Stock shall have been suspended by the SEC or the Nasdaq Capital Market or trading in securities generally on the New York Stock Exchange or the Nasdaq Stock Market shall have been suspended or limited or minimum prices shall have been established on either of such exchanges, (ii) a banking moratorium shall have been declared either by Federal or New York State authorities, (iii) there shall have occurred a material disruption in commercial banking or securities settlement or clearance services or (iv) there shall have occurred any outbreak or escalation of hostilities, declaration by the United States of a national emergency or war, or other calamity or crisis the effect of which on financial markets is such as to make it, in the sole judgment of the Representatives, impractical or inadvisable to proceed with the offering or delivery of the Securities as contemplated by the Preliminary Prospectus or the Prospectus (exclusive of any amendment or supplement thereto).

11. Representations and Indemnities to Survive. The respective agreements, representations, warranties, indemnities and other statements of the Company or its officers and of the Underwriters set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of any Underwriter or the Company or any of the officers, directors, employees, agents, affiliates or controlling persons referred to in Section 8 hereof, and will survive delivery of and payment for the Securities. The provisions of Sections 7 and 8 hereof shall survive the termination or cancellation of this Agreement.

12. Notices. All communications hereunder will be in writing and effective only on receipt, and, if sent to the Representatives, will be mailed, delivered or telefaxed to Citigroup Global Markets Inc. at 388 Greenwich Street, New York, New York 10013, Attention: General Counsel, facsimile number: +1 (646) 291-1469; Credit Suisse Securities (USA) LLC, 11 Madison Avenue, New York, New York 10010-3629, Facsimile: (212) 325-4296, Attention: IBCM-Legal; Stifel, Nicolaus & Company, Incorporated, 787 7th Avenue, 11th Floor, New York, NY 10019, Attention: [•]; or, if sent to Compass Therapeutics, Inc., will be mailed, delivered or telefaxed to 245 First Street, 3rd Floor, Cambridge, Massachusetts 02142, Attention: Vered Bisker-Leib.

13. Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto and their respective successors and the officers, directors, employees, agents and controlling persons referred to in Section 8 hereof, and no other person will have any right or obligation hereunder.

14. Jurisdiction. The Company agrees that any suit, action or proceeding against the Company brought by any Underwriter, the directors, officers, employees, affiliates and agents of any Underwriter, or by any person who controls any Underwriter, arising out of or based upon this Agreement or the transactions contemplated hereby may be instituted in any State or U.S. federal court in The City of New York and County of New York, and waives any objection which it may now or hereafter have to the laying of venue of any such proceeding, and irrevocably submits to the non-exclusive jurisdiction of such courts in any suit, action or proceeding.

15. Recognition of the U.S. Special Resolution Regimes.

(a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

As used in this Section 15, “BHC Act Affiliate” has the meaning assigned to the term “affiliate” in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k); “Covered Entity” means any of the following: (i) a “covered entity” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b), (ii) a “covered bank” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b) or (iii) a “covered FSI” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b); “Default Right” has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable; and “U.S. Special Resolution Regime” means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

16. No Fiduciary Duty. The Company hereby acknowledges that (a) the purchase and sale of the Securities pursuant to this Agreement is an arm’s-length commercial transaction between the Company, on the one hand, and the Underwriters and any affiliate through which it may be acting, on the other, (b) the Underwriters are acting as principal and not as an agent or fiduciary of the Company and (c) the Company’s engagement of the Underwriters in connection with the offering and the process leading up to the offering is as independent contractors and not in any other capacity. Furthermore, the Company agrees that it is solely responsible for making its own judgments in connection with the offering (irrespective of whether any of the Underwriters has advised or is currently advising the Company on related or other matters). The Company agrees that it will not claim that the Underwriters have rendered advisory services of any nature or respect, or owe an agency, fiduciary or similar duty to the Company, in connection with such transaction or the process leading thereto.

17. Integration. This Agreement supersedes all prior agreements and understandings (whether written or oral) between the Company and the Underwriters, or any of them, with respect to the subject matter hereof.

18. Applicable Law. This Agreement will be governed by and construed in accordance with the laws of the State of New York applicable to contracts made and to be performed within the State of New York.

19. Waiver of Jury Trial. The Company hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

20. Counterparts. This Agreement may be signed in one or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement.

21. Headings. The section headings used herein are for convenience only and shall not affect the construction hereof.

If the foregoing is in accordance with your understanding of our agreement, please sign and return to us the enclosed duplicate hereof, whereupon this letter and your acceptance shall represent a binding agreement among the Company and the several Underwriters.

Very truly yours,

Compass Therapeutics, Inc.

By: _____

Name:

Title:

[Signature Page to Underwriting Agreement]

The foregoing Agreement is hereby confirmed and accepted
as of the date first above written.

Citigroup Global Markets Inc.

By: _____

Name:

Title:

For itself and the other several Underwriters named in
Schedule I to the foregoing Agreement.

[Signature Page to Underwriting Agreement]

SCHEDULE I

Underwriters

Number of Underwritten
Securities to be Purchased

Citigroup Global Markets Inc.	
Credit Suisse Securities (USA) LLC	
Stifel, Nicolaus & Company, Incorporated	
Raymond James & Associates, Inc.	
Total	

SCHEDULE II

Schedule of Free Writing Prospectuses included in the Disclosure Package

II-1

SCHEDULE III

Schedule of Written Testing-the-Waters Communication

III-1

Compass Therapeutics, Inc.
Public Offering of Common Stock

[•], 2020

Citigroup Global Markets Inc.

Credit Suisse Securities (USA) LLC

Stifel, Nicolaus & Company, Incorporated
As Representatives of the several Underwriters,

c/o Citigroup Global Markets Inc.
388 Greenwich Street
New York, New York 10013

c/o Credit Suisse Securities (USA) LLC
11 Madison Avenue
New York, New York 10010

c/o Stifel, Nicolaus & Company, Incorporated
787 7th Avenue, 11th Floor
New York, NY 10019

Ladies and Gentlemen:

This letter is being delivered to you in connection with the proposed underwriting agreement (the "Underwriting Agreement"), between Compass Therapeutics, Inc., a Delaware corporation (the "Company"), and you as representatives (the "Representatives") of a group of Underwriters named therein, relating to an underwritten public offering of Common Stock, \$0.0001 par value (the "Common Stock"), of the Company (the "Offering").

In order to induce you and the other Underwriters to enter into the Underwriting Agreement, the undersigned will not, without the prior written consent of the Representatives, offer, sell, contract to sell, pledge or otherwise dispose of, (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise) by the undersigned or any affiliate of the undersigned or any person in privity with the undersigned or any affiliate of the undersigned), directly or indirectly, including the filing (or participation in the filing) of a registration statement with the Securities and Exchange Commission in respect of, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Securities and Exchange Commission promulgated thereunder with respect to, any shares of capital stock of the Company or any securities convertible into, or

exercisable or exchangeable for such capital stock, or publicly announce an intention to effect any such transaction, for a period from the date hereof until 180 days after the date of the Underwriting Agreement, other than shares of Common Stock disposed of as bona fide gifts approved by the Representatives where each recipient of a gift of shares agrees in writing to be bound by the same restrictions in place for the undersigned pursuant to this letter for the duration that such restrictions remain in effect at the time of transfer. If the undersigned is an officer or director of the Company, the undersigned further agrees that the foregoing restrictions shall be equally applicable to any issuer-directed shares of Common Stock the undersigned may purchase in the Offering.

If the undersigned is an officer or director of the Company, (i) the Representatives agree that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of shares of Common Stock, the Representatives will notify the Company of the impending release or waiver, and (ii) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver. Any release or waiver granted by the Representatives hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if (a) the release or waiver is effected solely to permit a transfer not for consideration and (b) the transferee has agreed in writing to be bound by the same terms described in this letter to the extent and for the duration that such terms remain in effect at the time of the transfer.

If for any reason the Underwriting Agreement shall be terminated prior to the Closing Date (as defined in the Underwriting Agreement), the agreement set forth above shall likewise be terminated.

Yours very truly,

By: _____
Name:
Title:

Compass Therapeutics, Inc.

[insert date]

Compass Therapeutics, Inc. (the "Company") announced today that [Citigroup Global Markets Inc.][Credit Suisse Securities (USA) LLC][Stifel, Nicolaus & Company, Incorporated], book-running manager in the Company's recent public sale of [•] shares of common stock, is [waiving] [releasing] a lock-up restriction with respect to [•] shares of the Company's common stock held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on *[insert date]*, 20__, and the shares may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

Compass Therapeutics, Inc.
Public Offering of Common Stock

[insert date], 20__

[name and address of officer or director requesting waiver]

Dear Mr./Ms. [insert name]:

This letter is being delivered to you in connection with the offering by Compass Therapeutics, Inc. (the "Company") of [•] shares of common stock, \$[•] par value (the "Common Stock"), of the Company and the lock-up letter dated [insert date], 2020 (the "Lock-up Letter"), executed by you in connection with such offering, and your request for a [waiver] [release] dated [insert date], 20__, with respect to [•] shares of Common Stock (the "Shares").

[Citigroup Global Markets Inc.][Credit Suisse Securities (USA) LLC][Stifel, Nicolaus & Company, Incorporated] hereby agrees to [waive] [release] the transfer restrictions set forth in the Lock-up Letter, but only with respect to the Shares, effective [insert date], 20__; provided, however, that such [waiver] [release] is conditioned on the Company announcing the impending [waiver] [release] by press release through a major news service at least two business days before effectiveness of such [waiver] [release]. This letter will serve as notice to the Company of the impending [waiver] [release].

Except as expressly [waived] [released] hereby, the Lock-up Letter shall remain in full force and effect.

Yours very truly,

[Citigroup Global Markets Inc.]
[Credit Suisse Securities (USA) LLC]
[Stifel, Nicolaus & Company, Incorporated]

By: _____
Name:
Title:

cc: Compass Therapeutics, Inc.

November 9, 2020

Compass Therapeutics, Inc.
245 First Street
3rd Floor
Cambridge, Massachusetts 02142

Re: Securities Registered under Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to you in connection with your filing of a Registration Statement on Form S-1 (File No. 333-249536) (as amended or supplemented, the "Registration Statement") pursuant to the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration of the offering by Compass Therapeutics, Inc., a Delaware corporation (the "Company") of up to 10,350,000 shares (the "Shares") of the Company's Common Stock, \$0.0001 par value per share, including Shares purchasable by the underwriters upon their exercise of an over-allotment option granted to the underwriters by the Company. The Shares are being sold to the several underwriters named in, and pursuant to, an underwriting agreement among the Company and such underwriters (the "Underwriting Agreement").

We have reviewed such documents and made such examination of law as we have deemed appropriate to give the opinions set forth below. We have relied, without independent verification, on certificates of public officials and, as to matters of fact material to the opinions set forth below, on certificates of officers of the Company.

The opinion set forth below is limited to the Delaware General Corporation Law.

Based on the foregoing, we are of the opinion that (i) the Shares have been duly authorized and, upon issuance and delivery against payment therefor in accordance with the terms of the Underwriting Agreement, the Shares will be validly issued, fully paid and non-assessable.

We hereby consent to the inclusion of this opinion as Exhibit 5.1 to the Registration Statement and to the references to our firm under the caption "Legal Matters" in the Registration Statement. In giving our consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

Very truly yours,

/s/ GOODWIN PROCTER LLP

GOODWIN PROCTER LLP

November 9, 2020

Securities and Exchange Commission
100 F Street NE
Washington, D.C. 20549

Ladies and Gentlemen:

We have read the section under the heading “Changes in and Disagreements with Accountants on Accounting and Financial Disclosure” included in Form S-1 of Compass Therapeutics, Inc., to be filed on or about November 9, 2020, and agree with the statements contained therein as they relate to our firm. We have no basis to agree or disagree with other statements of the registrant contained therein.

Respectfully submitted,

/s/ Raich Ende Malter & Co. LLP

Melville, New York

Consent of Independent Registered Public Accounting Firm

We consent to the inclusion in Amendment No. 1 to the Registration Statement on Form S-1 (file no. 333-249536) of Compass Therapeutics, Inc. of our report dated June 23, 2020 on our audits of the consolidated financial statements of Compass Therapeutics LLC and Subsidiary as of December 31, 2019 and 2018 and for the years then ended. We also consent to the reference to our firm under the heading "Experts."

/s/ CohnReznick LLP
Roseland, New Jersey
November 6, 2020