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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

Commission File Number 000-55939

Compass Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**82-4876496**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
80 Guest Street, Suite 601 Boston, Massachusetts	**02135**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	CMPX	Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☐		
Non-accelerated filer	☒	Smaller reporting company	☒
Accelerated filer	☐	Emerging growth company	☒

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates as of the last business day of its most recently completed second fiscal quarter (June 30, 2024), traded on the Nasdaq Capital Market in the United States under the symbol CMPX was approximately $98 million.

The number of shares of Registrant’s Common Stock outstanding as of February 15, 2025 was 138,282,498.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A relating to the 2024 Annual Meeting of Stockholders within 120 days of the end of the registrant's fiscal year ended December 31, 2024. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

Auditor Firm Id: 596 Auditor Name: CohnReznick LLP Auditor Location: Melville, NY U.S.A.

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RISK FACTOR SUMMARY

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 subsidiaries, including Compass Therapeutics LLC, Trigr Therapeutics, Inc. and Compass Therapeutics Securities Corporation, which we refer to as Compass Therapeutics. Our business is subject to numerous risks and uncertainties, including those described in Item 1A "Risk Factors". These risk factors include, but are not limited to 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 have never generated revenue from product sales and may never be profitable.
- 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.
- 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.
- 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.
- 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.
- 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.

- 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.

- 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.

- 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.

- 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.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Form 10-K") contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “would,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential,” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements contained in this report include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing and focus of our future clinical trials, and the reporting of data from those trials;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development;
- regulatory and commercialization expertise;
- our estimates of the number of patients who suffer from the diseases we are targeting and the number of patients that will enroll in our clinical trials;
- the size of the market opportunity for our product candidates in each of the diseases we are targeting;
- our ability to expand our product candidates into additional indications and patient populations;
- the success of competing therapies that are or may become available;
- the beneficial characteristics, safety, efficacy, and therapeutic effects of our product candidates;
- the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug or breakthrough therapy designation, for our product candidates for various diseases;

- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available and the outcome of our ongoing arbitration proceedings;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- our financial performance;
- the sufficiency of our existing cash, cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements; and
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act").

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations, and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this report and are subject to a number of risks, uncertainties, and assumptions described in the section titled "Risk Factors" and elsewhere in this report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. All forward-looking statements are made as of the date of this report and we do not undertake any obligation to update our forward-looking statements, except as required by applicable law.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

Investors and others should note that we may announce material business and financial information to our investors using our investor relations website (https://investors.compasstherapeutics.com), Securities and Exchange Commission ("SEC"), filings, webcasts, press releases, and conference calls. We use these mediums, including our website, to communicate with our members and public about our company, our products, and other issues. It is possible that the information that we make available may be deemed to be material information. We therefore encourage investors and others interested in our company to review the information that we make available on our website.

PART I

Item 1. Business.

Overview

We are a clinical-stage, oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics to treat multiple human diseases. Our scientific focus is on the relationship between angiogenesis, the immune system, and tumor growth. Our pipeline of novel product candidates is designed to target multiple critical biological pathways required for an effective anti-tumor response. These include modulation of the microvasculature via angiogenesis-targeted agents, induction of a potent immune response via activators on effector cells in the tumor microenvironment, and alleviation of immunosuppressive mechanisms used by tumors to evade immune surveillance. We plan to advance our product candidates through clinical development as both standalone therapies and in combination with proprietary pipeline antibodies based on supportive clinical and nonclinical data.

Our pipeline comprises three clinical product candidates and one candidate in investigational new drug application ("IND") enabling studies. Our lead product candidate, tovecimig (formerly known as CTX-009), is a bispecific antibody targeting Delta-like ligand 4 ("DLL4"), a ligand of Notch-1, and vascular endothelial growth factor A ("VEGF-A"). Simultaneous blockade of the VEGF-A and the Notch pathways is known to turn productive angiogenesis into non-productive angiogenesis, which leads to tumor shrinkage and apoptosis. Our second program CTX-471, is an agonistic antibody targeting a member of the tumor necrosis factor receptor superfamily member 9 (TNFRSF9), also known as CD-137, a co-stimulatory receptor which is mostly expressed on activated, but not on resting, T-cells and NK cells. Our third program, CTX-8371, is a bispecific antibody targeting the programmed cell death protein-1 ("PD-1"), an inhibitory immune checkpoint receptor and its ligand PD-L1, two validated immune-oncology targets. In addition, we are in the process of IND enabling studies with CTX-10726, a bispecific antibody targeting PD-1 and VEFG-A.

Tovecimig (CTX-009), our bispecific antibody targeting DLL4 and VEGF-A, is currently being evaluated in a randomized Phase 2/3 trial in the United States in combination with paclitaxel in patients with biliary tract cancer ("BTC") who received one prior treatment regimen. We expect top-line data from this study at the end of the first quarter of 2025. In August 2024, we also announced that tovecimig demonstrated a 5% overall response rate ("ORR") as a monotherapy in our Phase 2 study of patients with advanced, metastatic colorectal cancer ("CRC").

The two initial indications of BTC and CRC for tovecimig were selected based on the results of the Phase 1,1b and 2 clinical trials and the significant unmet need for effective therapeutic regimens in these patient populations. We estimate that there are approximately 23,000 patients diagnosed with BTC in the United States each year and over 200,000 patients worldwide. Patients with BTC have a poor prognosis despite first-line treatment with chemotherapy and immunotherapy, and there is no generally accepted standard of care in later lines of treatment, except for therapies for targeted mutations, which is estimated to be approximately 15% of the market. For CRC, there are approximately 153,000 new patients diagnosed each year in the United States and more than 1.9 million patients worldwide. Despite advances in treatment of CRC in recent years with angiogenesis inhibitors and targeted therapies, there are few safe and effective treatment options for patients with CRC, and the majority of the patients are refractory to existing therapeutic regimens or relapse quickly and advance to later lines of therapy where treatment options are more limited and less effective. We also intend to expand the development of tovecimig to additional indications with significant unmet need such as ovarian cancer and gastric cancer. Following the generation of positive clinical data in later lines of therapy, we plan to study tovecimig in earlier settings in all indications where the data support it.

CTX-471, our CD137 agonistic antibody, targets a key node of the immune system with the goal of becoming a next generation immune-oncology treatment for patients across a variety of cancers who do not have a sustained response to current therapies. During its early clinical development, CTX-471 demonstrated monotherapy activity in the post-PD-1/PD-L1 patient population across three solid tumor indications: melanoma, small cell lung cancer ("SCLC") and mesothelioma. The Phase 1 program, which included one complete response, also identified a potential biomarker of activity for CTX-471, neural cell adhesion molecule (NCAM or CD56). We expect to initiate a Phase 2 basket study of CTX-471 in patients with NCAM+ tumors in mid-2025.

CTX-8371, our bispecific antibody targeting PD-1 and PD-L1, is currently in a first-in-human Phase 1 clinical trial. CTX-8371 emerged from an unbiased screen for synergy conducted with our StitchMabs™ platform. We subsequently tested CTX-8371 in several in vitro and in vivo models where it demonstrated enhanced activation of immune responses when compared with commercially available checkpoint blockers. We believe that CTX-8371 has the potential to become a next generation checkpoint inhibitor with improved activity across various solid tumors relative to approved checkpoint blockers. We expect to complete our Phase 1 study of CTX-8371 in the second half of 2025.

Finally, CTX-10726, our bispecific antibody targeting PD-1 and VEGF-A, is currently in IND enabling studies, with an IND filing expected by year end 2025. CTX-10726 is a fully human IgG1 with silenced Fc-γ receptor binding that was discovered and developed in-house. We expect to accelerate the development of CTX-10726 by leveraging our experience developing and manufacturing bispecific structures containing VEGF-A (tovecimig) and PD-1 (CTX-8371) components.

Pipeline

The figure below details our pipeline of product candidates.



Our Strategy

Our scientific focus is on the relationship between angiogenesis, the immune system, and tumor growth. Our pipeline of novel product candidates is designed to target multiple critical biological pathways required for an effective anti-tumor response. Our strategy to achieve this goal includes:

- **Advance our product candidate, tovecimig (DLL4 x VEGF-A bispecific antibody), through clinical development and potential commercialization for multiple indications**. Tovecimig is an investigational bispecific antibody that simultaneously blocks the DLL4 and VEGF-A signaling pathways, which are critical to angiogenesis and tumor vascularization. We chose BTC and CRC as our first indications based on a number of factors, including tovecimig's activity observed in the Phase 1, 1b and 2 clinical trials and the lack of effective therapies for these patient populations. We completed enrollment of a randomized Phase 2/3 trial of tovecimig in combination with paclitaxel in patients with BTC and a Phase 2 trial of tovecimig in patients with advanced CRC. In addition, an investigator sponsored trial of tovecimig in the first-line setting in combination with gemcitabine/cisplatin and durvalumab in patients with BTC was initiated in the first quarter of 2025. We intend to explore the potential of tovecimig in other indications where the data support its potential therapeutic benefit such as ovarian cancer, gastric cancer, renal cell cancer, and liver cancer.

- **Advance our product candidate, CTX-471 (CD137 agonist antibody), through clinical development to evaluate its therapeutic potential and define a regulatory pathway for approval.** We seek to translate the antitumor activity of CTX-471 observed in preclinical testing and in our Phase 1 trial into meaningful clinical results in patients with solid tumors, such as SCLC, non-small cell lung cancer ("NSCLC") and melanoma. Our Phase 1a clinical trial was conducted in patients who relapsed or progressed after at least three months of a prior checkpoint therapy. As of January 31, 2025, two patients remain on trial. During the Phase 1a trial, we identified a potential biomarker of activity, neural cell adhesion molecule (NCAM or CD56), which we intend to use in a Phase 2 basket study of CTX-471, expected to start in mid-2025.

- **Advance CTX-8371 (PD-1 x PD-L1 bispecific antibody) through clinical development as a next generation checkpoint inhibitor.** CTX-8371 has demonstrated better antitumor activity in preclinical experiments than a single PD-1, a single PD-L1, or combinations of PD-1 and PD-L1 inhibitors. We initiated a first-in-human Phase 1 clinical trial with the first patient dosed in April 2024. As of January 2025, the third cohort of this trial completed with no dose limiting toxicities observed.

- **Advance CTX-10726 (PD-1 x VEFG-A bispecific antibody) through IND-enabling studies and clinical development.** CTX-10726 was developed at Compass leveraging our experience with the VEGF-A component of tovecimig and the PD-1 component of CTX-8371. We are currently performing IND enabling studies and anticipate filing an IND by year end 2025.

- **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 development, clinical development and commercialization of these candidates in a capital-efficient manner, including selectively pursuing strategic partnerships with leading biopharmaceutical companies with domain-specific clinical development and commercial expertise to maximize the value of our pipeline.

Product Candidates

We currently have three product candidates in the clinical stage of development: tovecimig, CTX-471 and CTX-8371. Additionally, we have one product candidate in IND enabling studies, CTX-10726.

Tovecimig (DLL4 X VEGF-A bispecific antibody)

Tovecimig (formerly known as CTX-009) is an investigational bispecific antibody that is designed to simultaneously block the DLL4 and VEGF-A signaling pathways, which are critical to angiogenesis and tumor vascularization. Preclinical and early clinical data of tovecimig as a monotherapy and in combination with chemotherapy suggest that blockade of both pathways provides robust anti-tumor activity across several solid tumor indications, including colorectal, gastric, cholangiocarcinoma, pancreatic and NSCLC.

Tovecimig is undergoing clinical development in patients with advanced solid tumors in the United States. A Phase 1 dose escalation and dose expansion monotherapy trial in patients with solid tumors, a Phase 1b trial of tovecimig in combination with chemotherapy and a Phase 2 trial of tovecimig in combination with chemotherapy in patients with advanced biliary tract cancer were completed in South Korea. Data from the Phase 2 trial were presented at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium ("ASCO GI") in January 2023.

We are currently conducting a randomized Phase 2/3 trial of tovecimig in combination with paclitaxel in patients with advanced BTC. In addition, an investigator sponsored trial of tovecimig in the first-line setting in combination with gemcitabine/cisplatin and durvalumab in patients with BTC was initiated in the first quarter of 2025, led by investigators at The University of Texas MD Anderson Cancer Center.

We have licensed exclusive global rights to tovecimig, outside of South Korea, from ABL Bio, Inc. ("ABL Bio"), a South Korea-based clinical-stage company focused on developing antibody therapeutics. South Korean rights are held by Handok Pharmaceuticals, Inc. ("Handok") and China rights were out-licensed from us to Elpiscience Biopharmaceuticals Co., Limited ("Elpiscience").

Phase 1 Summary of Clinical Activity of Tovecimig at the Recommended Phase 2 Dose (RP2D) – South Korea

The observed ORR of tovecimig at the 10 and 12.5 mg/kg doses were 18.8% (3/16) as a monotherapy and 23.5% (4/17) in combination with chemotherapy. The clinical benefit rate ("CBR") of tovecimig at the 10 and 12.5 mg/kg were 68.8% (11/16) as a monotherapy and 76.5% (13/17) in combination with chemotherapy.

In October 2021, we, along with ABL Bio, presented clinical trial data from the tovecimig Phase 1a/1b dose escalation and dose expansion trial at a plenary oral session during the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics (Abstract Number: 4749; Session title: Plenary Session 2: New Drugs on the Horizon I). The significant findings presented were as follows:

- Tovecimig was generally well-tolerated and demonstrated single agent activity in heavily pre-treated patients with solid tumors who were resistant to anti-VEGF therapies, mostly of colorectal and gastric origins
- The maximum tolerated dose ("MTD") was not reached, and the RP2D of tovecimig were determined to be 10.0 and 12.5 mg/kg biweekly
- ORR of tovecimig as a monotherapy across all doses tested (0.3 – 17.5 mg/kg) was 8% and the CBR was 62% in patients treated at the 3rd and 4th line settings
- Treatment with tovecimig as a monotherapy at the RP2D (10.0 mg/kg and 12.5 mg/kg) led to 18.8% (n=3/16) ORR, not including an additional unconfirmed PR, and a 68.5% CBR (n=11/16)

Phase 2 Trial of Tovecimig with Paclitaxel in BTC - South Korea

In the Phase 1b Study, there were four patients enrolled with cholangiocarcinoma. Two of these four patients had deep, durable, and confirmed responses. Both of these patients received tovecimig in combination with paclitaxel. Based on this observation, a Phase 2 trial of tovecimig in combination with paclitaxel was completed by ABL Bio in patients with BTC, with data reported in the first quarter of 2023. The trial enrolled patients with unresectable advanced, metastatic, or relapsed BTC who had received one or two prior systemic therapies.

This Phase 2 trial utilized a Simon Two-Stage adaptive design where the criteria to advance to the second stage of the trial was three PRs observed in 21 evaluable patients. In the preliminary analysis of all 24 patients participating in the study, tovecimig with paclitaxel demonstrated a 37.5% ORR based on 9 patients with PRs that were confirmed by RECIST 1.1. The results of Part 1 of the Phase 2 trial were presented at the 2024 ASCO GI meeting in January 2024.

Based on the efficacy data and following discussions with the U.S. Food and Drug Administration ("FDA"), while the trial had met the criteria to advance to Part 2, we elected to terminate the study and advance tovecimig directly to a randomized Phase 2/3 study in patients with BTC treated in the second-line setting.

Safety Data Summary

Tovecimig safety data has been analyzed and was observed to be generally well-tolerated. Of the 24 patients enrolled in the first stage of the trial, all patients had at least one treatment emergent adverse event ("TEAE"). Grade 3 or greater TEAEs were reported in 95.8% of patients regardless of the relationship to tovecimig or paclitaxel, including decreased neutrophil count (83.3%), hypertension (16.7%), anemia (20.8%), and decreased platelet count (12.5%). Grade 3 or greater adverse events that were designated to be of special interest ("AESIs") by the trial investigators were hemoptysis or hemorrhage (12.5%) and GI or tumor perforation (8.3%), with 0% for pulmonary hypertension, wound healing complication and cardiac failure.

The table below depicts a summary of the TEAEs in 24 patients for the study.

Treatment Emergent Adverse Events observed in > 1 patient	**Total (n)**	**Total (%)**	**Grade 3 (n)**	**Grade 3 (%)**
Neutrophil count decreased	22	92	20	83
Hypertension	12	50	4	17
Platelet count decreased	9	38	3	13
Anaemia	5	21	5	21
Ascites	4	17	2	8
Decreased appetite	4	17	2	8
Neutropenia	2	8	2	8
Liver abscess	2	8	2	8
Hepatic infection	2	8	2	8
Cholangitis	2	8	2	8
Embolism	2	8	2	8

Activity Data Summary

The first stage of the trial enrolled 24 patients and 22 of those patients were considered evaluable.

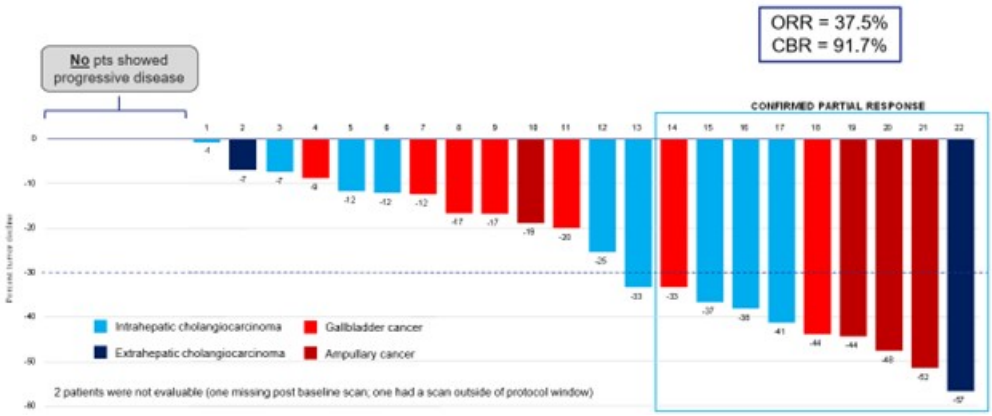
Nine PRs confirmed by RECIST 1.1 were observed leading to an ORR of 37.5%, and 22 of the 24 patients evaluated have had stable disease or better with a decline in tumor burden leading to a CBR of 92%. PRs were observed in all four tumor sub-types types (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, gallbladder cancer, and ampullary carcinoma). Of the 24 patients, 11 were treated in the second line with 7 PRs observed, leading to an ORR of 63.6% in this sub-group. In the third line, 13 patients were treated with 2 PRs observed, leading to an ORR of 15.4% in the second sub-group.

After a median follow up of approximately 12 months, the median progression free survival ("PFS") was 9.4 months, median duration of response ("DOR") was 6.9 months and median overall survival ("OS") was 12.5 months.

For reference, one regimen that has been studied in patients with advanced BTC is the three-drug combination FOLFOX. FOLFOX demonstrated an ORR of 5%, a median PFS of 4.0 months, and a median OS of 6.2 months in a randomized study against best supportive care.

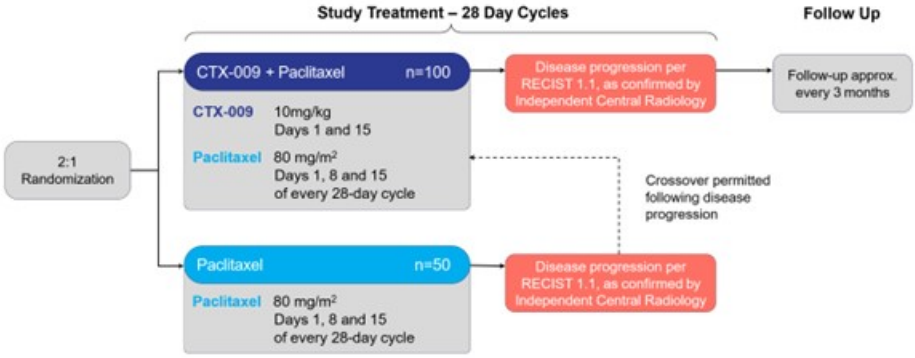
The waterfall plot below depicts the best response for the 22 patients evaluated in the trial.

Phase 2 Data
tovecimig + paclitaxel in BTC
Best Response by Patient



Phase 2/3 Trial of Tovecimig with Paclitaxel in BTC – United States

Following conversations with the FDA, we submitted a protocol for a randomized Phase 2/3 trial for tovecimig in combination with paclitaxel in adult patients with unresectable, advanced, metastatic or recurrent biliary tract cancers who have received one prior systemic chemotherapy regimen. The trial is designed to assess the safety and efficacy of the combination of tovecimig and paclitaxel versus paclitaxel alone. A schema of the trial design is provided below:



The trial was designed to enroll 150 patients, randomized in a 2:1 ratio to receive tovecimig plus paclitaxel (n=100) or paclitaxel alone (n=50). The primary endpoint of the trial is ORR and the secondary endpoints include PFS, OS, DOR and DCR among others. Patients who were randomized to receive paclitaxel and have progressed on their regimen can cross over to the tovecimig plus paclitaxel arm after progression on paclitaxel if they still meet the enrollment criteria for the study. A detailed description of the trial can be found on www.clinicaltrials.gov (Identifier NCT 05506943).

This trial was fully enrolled in August 2024. Top line data is expected at the end of the first quarter of 2025.

Phase 2 Trial of Tovecimig in CRC – United States

We conducted a Phase 2 monotherapy clinical trial of tovecimig in patients with metastatic colorectal cancer who have received two or three prior systemic therapies. This trial was designed to assess the safety and efficacy of tovecimig as a monotherapy in patients with advanced CRC. The trial utilized a Simon Two-Stage adaptive design where the criteria to advance to the second stage of the trial was three PRs observed in 37 patients enrolled in Stage 1 of the trial.

The first stage of the trial enrolled 41 patients in the United States, of which 26 (63%) were treated in the fourth line. Tovecimig demonstrated an ORR of 5% (2 out of 41), a DCR of 71% (29 out of 41), median PFS of 3.9 months and median overall survival ("OS") of 10.2 months. The safety profile was consistent with the prior clinical trials with hypertension as the most common adverse event. The ORR did not meet the criteria to advance to the second stage of the trial, but based on this efficacy signal we are planning to initiate a new second-line trial of tovecimig. We are evaluating the details of this study to investigate tovecimig in combination with chemotherapy in patients with metastatic CRC based on DLL4 positivity and expect to initiate it in mid-2025.

Additional Plans for Tovecimig

We intend to explore the potential of tovecimig in additional indications, based on data from pre-clinical models, potential biomarkers such as DLL4, and clinical data from tovecimig trials providing signs of potential activity of tovecimig in additional indications such as ovarian cancer, gastric cancer,, renal cell cancer, and liver cancer.

In addition, we are developing a plan to study the combination of tovecimig with our novel bispecific checkpoint blocker, CTX-8371, and with other checkpoint blockers, such as pembrolizumab and atezolizumab. Additionally, we are considering the combination of tovecimig with our novel CD137 agonistic antibody, CTX-471.

CTX-471 (CD137 agonist antibody)

CTX-471, our monoclonal antibody product candidate, is a fully human, IgG4 monoclonal antibody that is an agonist of CD137, a key co-stimulatory receptor on immune cells. Binding of CTX-471 to CD137 has been observed to lead to ligand-stimulated activation of T-cells and NK cells. In treated mice, dosing with CTX-471 led to extensive reprogramming of the tumor microenvironment, including increased recruitment of immune cells, reversal 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 equal to eight half-lives of the antibody, treated mice exhibited immune memory that prevented reestablishment of the same tumor.

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 the antibody using different backbones and chose to use a human IgG4 backbone for CTX-471 to enable engagement of Fc receptors FcγRI and FcγRIIb to facilitate CD137 cross-linking while avoiding binding to FcγRIIIa and depletion of immune effector cells through ADCC.

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. We also observed that tumors treated with CTX-471 had an approximate two-fold reduction in the number of immunosuppressive tumor-associated macrophages.

In addition, we have observed potent activity in other syngeneic tumor models including 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 the ability of CTX-471 to transform the tumor microenvironment through the combined action of immune cell recruitment, alleviation of T-cell exhaustion, suppression of Tregs, and reduction of tumor suppressing macrophages leads to CTX-471's antitumor activity in mouse models.

Phase 1 Clinical Trial of CTX-471

In a Phase 1b monotherapy study, CTX-471 was evaluated in patients with solid tumors that had progressed after at least three months on an approved PD-1 or PD-L1 inhibitor. Initial results reported from the study included five clinical responses, including a durable PR in a patient with SCLC that converted to a complete response (as confirmed by PET scan) and four additional PRs (one unconfirmed) in patients with melanoma and mesothelioma. The ORR in the subset of patients with advanced melanoma was 27% (3 of 11). Data were presented at the American Society of Clinical Oncology ("ASCO") Annual Meeting in June 2024.

Phase 1 Clinical Trial Data

In July 2019, we initiated a Phase 1 trial evaluating the safety and tolerability of CTX-471 as a monotherapy in patients with solid tumors 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 included a Phase 1a dose escalation stage followed by a Phase 1b dose expansion stage.

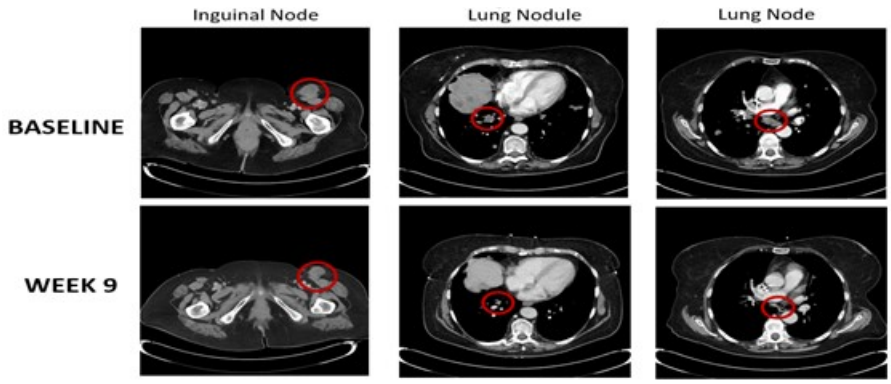
In the Phase 1a dose escalation, CTX-471 was observed to be generally well-tolerated in the Phase 1a stage of the trial. The dose-limiting toxicity was two thrombocytopenia based on two observed events in Cohort 4, which was expanded from three to six patients to collect additional safety data. Based on these results, 0.6 mg/kg was determined to be the maximum tolerated dose.

Phase 1b Dose Expansion

The dose expansion stage of the trial is completed. 60 patients with 17 different cancers were enrolled in the trial. One patient (noted below) had a CR and four additional patients had a PR. Of the four PRs observed in this dose expansion cohort, three PRs have been confirmed by RECIST 1.1 and the fourth PR was unconfirmed. There have been nine SAEs related to CTX-471 in the dose expansion stage of the trial. All nine events resolved.

The responses observed as described below:

- A PR was observed in a patient with metastatic melanoma who was previously treated with nivolumab and progressed on nivolumab. Below is a series of CT scan images from this patient. The patient had multiple metastases at baseline and reached a PR based on a 38% decline in linear tumor burden at week nine. This PR was confirmed at week 17.

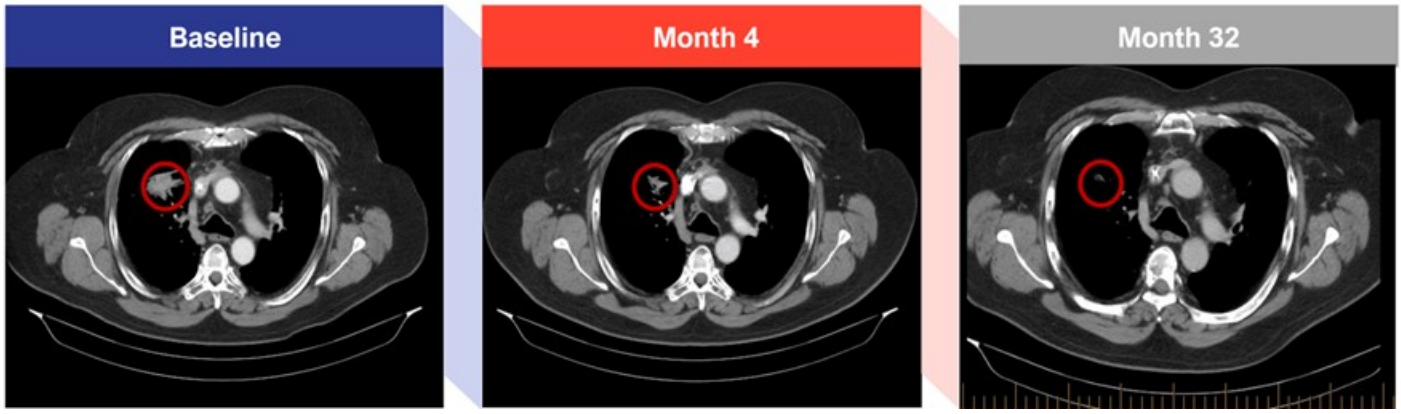


- A PR was observed in a patient with metastatic melanoma of mucosal origin who was previously treated with first-line regimen of ipilimumab plus nivolumab followed by second-line nivolumab as a monotherapy. After progressing on the prior regimens, the patient had joined the trial with multiple metastases at baseline. This patient reached a PR based on a 58% decline in linear tumor burden at week 17. This PR was not confirmed.

- A PR was observed in a patient with mesothelioma. This response was confirmed by RECIST 1.1.

- A PR was observed in a patient with melanoma treated in the third line setting. This response was confirmed by RECIST 1.1. This patient has been on the study for more than 2 years and is still ongoing.

- The CR was observed in a patient with advanced SCLC who was previously treated with the carboplatin/etoposide and atezolizumab (a PD-L1 blocker) regimen in the first line followed by a treatment with nivolumab (a PD-1 blocker) in the second line. After progression on prior regimens this patient joined the trial and had a PR at week 17 which was confirmed at week 25. This patient was dosed with CTX-471 for more than three years with a durable PR, and in Q4 2023, following tumor regression observed by CT-Scan, the patient was tested by PET scan and a CR was determined. Below is a series of CT scan images from this patient of the largest mass (RUL Lung) which was ~4 cm at baseline.



Of note, out of the five responses observed in this trial, three responses were in patients with melanoma, leading to a response rate of 27% in this subgroup of melanoma patients (3 out of 11). The other responses were in mesothelioma (1 out of 4) and SCLC (1 out of 3).

Biomarker discovery

In November 2024, we presented novel biomarker data associated with CTX-471 at the 39th Society for Immunotherapy of Cancer ("SITC") Annual Meeting. Our research showed a correlation between the levels of neural cell adhesion molecule ("NCAM" or CD56) in baseline tumor cell biopsies and disease control in patients treated with CTX-471. To measure pharmacodynamic effects, comparisons were made between pre- and post-CTX-471 treatment. To survey response biomarkers, values from baseline samples obtained from patients with tumors showing complete or partial responses as well as stable disease were compared with tumors showing progressive disease. We hypothesize that NCAM facilitates responses to CTX-471 by enriching for activated NK cells expressing the CTX-471 target, CD137. The dataset shows these effects to be specific for NCAM expressing lymphocytes such as NK cells and is not observed in other lymphocyte subsets such as CD8 T cells. These findings are novel in a clinical setting and support potential use of NCAM as a selection marker.

Development Plans for CTX-471

Based on the results of the monotherapy and combination arms of the Phase 1 trial, we are currently evaluating the design of a Phase 2 study of CTX-471 using NCAM as a biomarker, which we expect to initiate in mid-2025.

CTX-8371 (PD-1 x PDL-1 Bispecific Antibody)

CTX-8371 is a bispecific antibody that binds to both PD-1 and PD-L1, the targets of well-known and widely used checkpoint inhibitor antibodies. 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 treatment with a PD-1 inhibitor alone, a PD-L1 inhibitor alone or the combination of PD-1 and PD-L1 inhibitors. IND-enabling studies on CTX-8371, including GLP toxicology studies in non-human primates ("NHPs") were completed in the first quarter of 2023. The FDA cleared the IND for CTX-8371 in the fourth quarter of 2023 and the first patient in the Phase 1 clinical trial was dosed in April 2024.



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

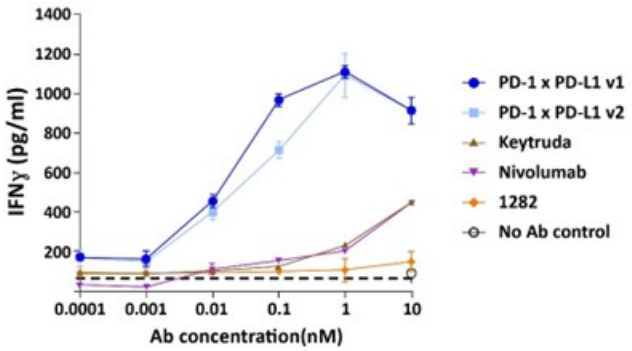
Overview of PD-1 and PD-L1 Checkpoint Inhibitors

PD-L1 is a surface protein that is overexpressed by over 35% of certain types of cancer, such as melanoma, hepatocellular carcinoma, CRC, 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, SCLC, head and neck squamous cell cancer, renal cell carcinoma, 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 2023 were estimated to be $48 billion. There is no approved therapy that combines inhibition of both PD-1 and PD-L1 in the same molecule.

Discovery and Preclinical Activity for 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 CTLA-4, LAG-3 or CD137. 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 approximately 40 potential immune targets across the innate and adaptive immune system.

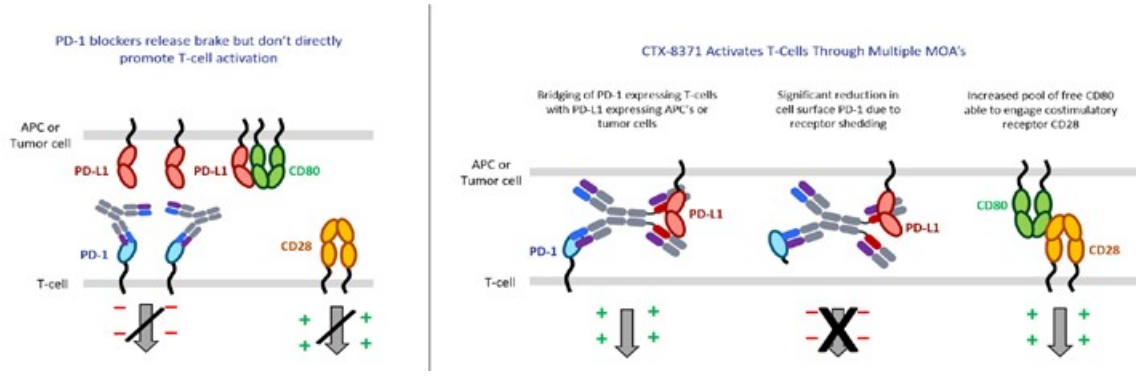
We designed our combinatorial screen such that one antigen-binding domain was directed against PD-1, and the other selected from our library of candidate antibodies. We screened these StitchMabs™ bispecific constructs in T-cell activation assays in the presence of PD-L1 expressing cells. Our unbiased 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 only PD-1 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 domain.



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

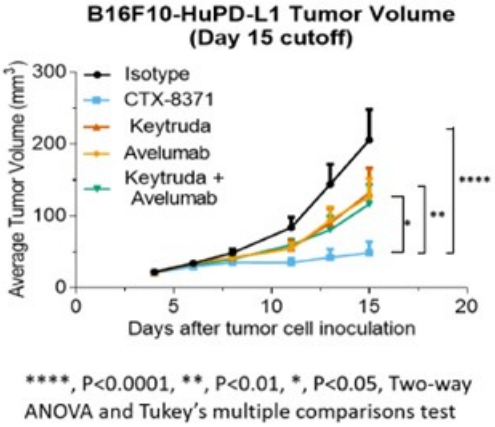
The observation that the combination of a PD-1 and PD-L1 antibody into a bispecific antibody would be hundreds to thousands fold more potent in a T-cell activation assay than a PD-1 antibody alone was unexpected. A simple model would suggest that inhibiting either PD-1 or PD-L1 should have approximately 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:

- **Dual checkpoint blocker**: preventing PD-L1 to PD-1 binding, thus relieving the immunosuppressive PD-1 signal;
- **Cell engager**: bridging the connection between the PD-L1 expressing tumor cell and the PD-1 expressing T-cell, potentially facilitating T-cell engagement and enhancement of effector function;
- **Downregulation of PD-1**: 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
- **Indirect CD28 agonist:** increasing the pool of free CD80 on tumor cells making it available to bind and activate the CD28 T-cell co-stimulatory receptor, thereby, sending a positive signal to the T-cell, which enhances its activation.

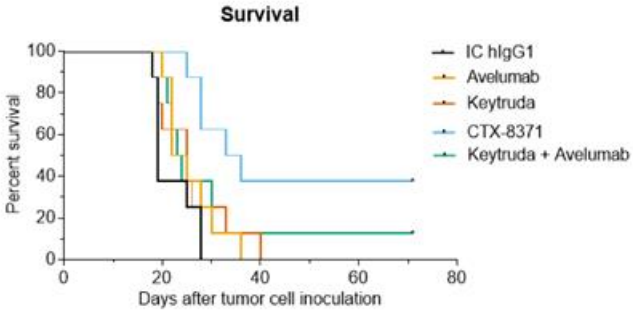


Differentiated mechanism of action of CTX-8371 drives enhanced T-cell activation

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 a 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.

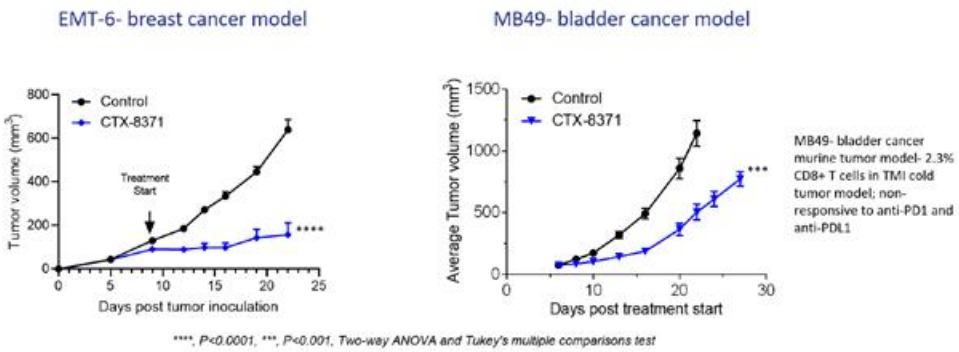


Tumor growth inhibition was improved when treating mice with CTX-8371 compared to treating them with monoclonal antibodies that inhibited either PD-1, PD-L1, or the combination of PD-1 and PD-L1



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.



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

In April 2022, we presented preclinical data on CTX-8371's potential unique mechanism of action ("MOA") that involves cleavage of cell surface PD-1, at the 2023 American Association for Cancer Research ("AACR") annual meeting. A summary of the results are as follows:

- Treatment with CTX-8371 led to PD-1 loss from the surface of intra-tumoral T cells in tumor-bearing transgenic hPD-1/h-PD-L1 mice, and on peripheral blood T cells in cynomolgus monkeys; this unique MOA differentiates CTX-8371 from marketed inhibitors targeting either PD-1 or PD-L1
- Clearance and half-life of CTX-8371 were within the expected ranges for a human IgG1 antibody in NHPs with a linear PK
- Treatment with CTX-8371 in the aggressive MC38-hPD-L1 colorectal mouse model led to a dose-proportional reduction in tumor volume and a complete eradication of tumors at the highest dose
- Taken together, the murine and cynomolgus monkey PK data, receptor occupancy data, and in vivo efficacy data in murine models was used to calculate the predicted human efficacious dose range for CTX-8371

Phase 1 and Development Plans for CTX-8371

We submitted an IND to the FDA in the third quarter of 2023. This IND was cleared by the FDA in October 2023. In the first quarter of 2024 we initiated a first-in-human Phase 1 study of CTX-8371 in patients with metastatic or locally advanced malignancies. This Phase 1 trial is a multiple ascending, dose escalation and there are five doses planned in this study: 0.1, 0.3, 1.0, 3.0 and 10 mg/Kg. Patients eligible to participate in the trial are patients who progressed while receiving an approved PD-1 or PD-L1 inhibitor. Other eligibility criteria include patients with metastatic of locally advanced melanoma, non-small cell lung cancer, head and neck cancer, Hodgkin's Lymphoma and triple negative breast cancer. As of January 2025, the third cohort of this trial was fully enrolled with no dose limiting toxicities observed. Initial data from the trial is expected in the second half of 2025.

CTX-10726 (PD-1 x VEGF-A Bispecific Antibody)

CTX-10726 is a novel, tetravalent PD-1 x VEGF-A bispecific antibody that we discovered, engineered and developed since 2023. CTX-10726 is designed to synergistically deliver VEGF-A blockade and checkpoint inhibition, which is potentially applicable to multiple solid tumor indications.

CTX-10726 utilizes a fully human, glycosylated IgG1 with silenced Fc-γ receptor binding and demonstrates a highly stable structure with high affinity target binding. Based on preclinical studies, CTX-10726 exhibits several-fold more potent PD-1 blockade compared with publicly available data reported for other drugs in the class, and we believe this may be a key differentiator from comparable bispecifics.

The development of CTX-10726 was informed and accelerated by our experience with two of our clinical-stage assets: tovecimig, which contains a VEGF-A targeted component, and CTX-8371, which contains a PD-1 targeted component. We are continuing IND-enabling studies and expect to file an IND by the end of 2025.



CTX-10726 is a PD-1 x VEGF-A bispecific antibody

Early-Stage Discovery

Traditionally, our approach to early-stage discovery has been 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 our proprietary StitchMabs™ technology that allows us to rapidly evaluate the potential of the antibodies we discover in a bispecific antibody format.

We have also developed a proprietary transgenic mouse line 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.

We have 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:

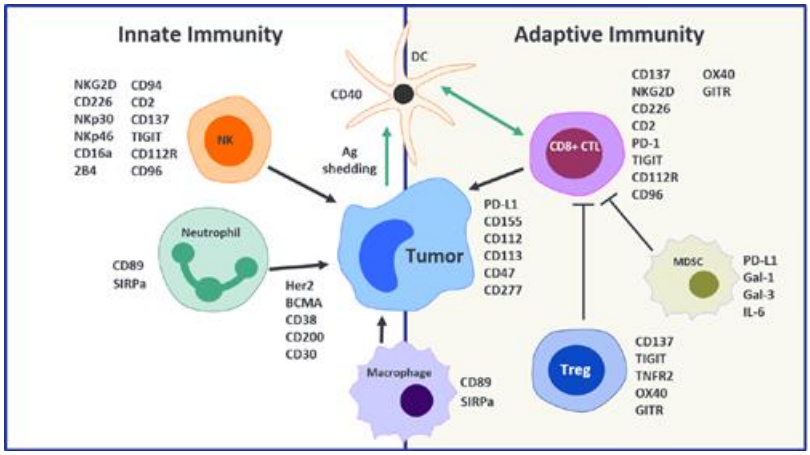
- antibody diversity is required to generate a representative sample of possible therapies;
- functional screening is critical to identifying optimal solutions;
- a combinatorial approach enables parallel assessment of many potential bispecific antibodies; and
- decisions made at the start of the discovery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

Antibody diversity

We obtained our initial pools of antibodies from multiple internally-developed platforms, including our custom phage display library and our transgenic mouse line. We constructed our phage display library based on the peripheral B cell diversity of 70 healthy human donors. This system allows us to generate large and highly diverse sets of antibodies that are fully human; target multiple epitopes on a target of interest; and possess excellent physical and biochemical properties. We describe these antibodies as having good 'drug-like' properties. To generate additional antibody candidates, we can also immunize a proprietary line of humanized transgenic mice with antigens of interest to isolate a diverse set of fully human antibodies that share a common human light chain, but distinct native mouse heavy chains. We estimate that the pool of antibodies from these two platforms represents over 1010 unique sequences.

We have expressed 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.



We have discovered proprietary antibodies that modulate two key components of the immune system: innate immunity and adaptive immunity as well as antibodies to selected antigens on tumor cells. This expansive collection of antibodies allows us to use our proprietary technologies to uncover unexpected synergies.

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.

StitchMabs™ Technology

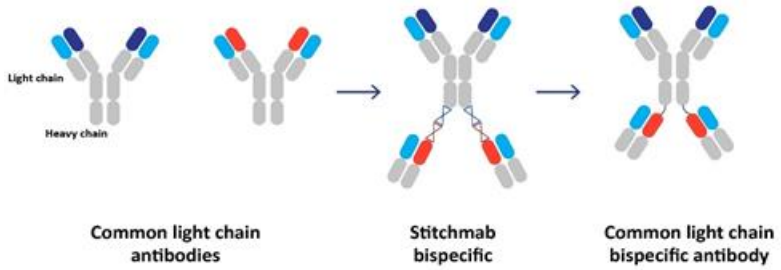
A natural antibody recognizes a single target antigen and is therefore monospecific. Because a natural antibody features two identical binding sites, it is considered bivalent for that target. Although natural antibodies recognize a single target antigen, it is possible to engineer antibodies so that 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 models.

Common Light Chain Platform

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 candidates into bispecific antibody product candidates.



A common light chain simplifies the production of bispecific antibodies

License Agreements

Tovecimig (DLL4 X VEGF-A bispecific antibody)

Our wholly owned subsidiary Trigr Therapeutics, Inc. ("TRIGR") and ABL Bio, a South Korean biotechnology company, entered into an exclusive global (excluding South Korea) license agreement (the "TRIGR License Agreement") which granted TRIGR a license to ABL001, ABL Bio's bispecific antibody targeting DLL4 and VEGF-A (renamed CTX-009 and subsequently tovecimig). Under the terms of the agreement, ABL Bio and TRIGR would jointly develop tovecimig, with ABL Bio responsible for development of tovecimig throughout the end of Phase 1 clinical trials and TRIGR responsible for the development of tovecimig from Phase 2 and onward.

ABL Bio received a $5 million upfront payment and a $6 million milestone payment. In addition, ABL Bio is eligible to receive up to $96 million of development and regulatory milestone payments, up to $303 million of commercial milestone payments and tiered single-digit royalties on net sales of tovecimig in oncology. ABL Bio is also eligible to receive up to $75 million in development and regulatory milestone payments and up to $110 million in commercial milestone payments and tiered, single-digit royalties on net sales of tovecimig in ophthalmology. The financial terms of the agreement were amended in May 2021 but remain substantially similar to the terms in the TRIGR License Agreement. As a result of the TRIGR acquisition, we have assumed all the rights and obligations of the TRIGR License Agreement.

CTX-471 (CD137 agonist antibody)

We entered into an amended and restated collaboration agreement with Adimab, LLC ("Adimab"), dated February 11, 2015, as amended. This agreement relates to our license from Adimab for certain antibodies for development and commercialization as biopharmaceutical products, including our product candidate, CTX-471. We were granted an exclusive option to license and potentially acquire antibodies under the agreement, which we exercised with respect to CTX-471. We are required to make payments upon achievement of development milestones that, as of December 31, 2024, 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.

Intellectual Property

Overview

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

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

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

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

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional application which matures into a granted patent. A U.S. patent also may be accorded a patent term adjustment ("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. As of January 31, 2025, we have greater than 90 issued patents and patent applications pending in the United States and foreign jurisdictions relating to tovecimig, CTX-471, CTX-8371, CTX-10726 and other discovery and research programs. We have 7 patents issued in the United States and issued patents in Taiwan, China, Eurasia, Japan, Korea, Malaysia, Singapore and New Zealand related to our CTX-471 program, and 2 patents issued in the United States, and issued patents in China, Japan and Taiwan, related to our CTX-8371 program. We also have access to patents issued in Australia, Europe and the United States related to our antibody and display programs, as well as 27 patents issued in Australia, Canada, China, Europe, Japan, Korea, Russia and 2 in United States related to our tovecimig program.

More specifically, we have licensed 2 patent families with 2 issued patents in U.S. and 27 issued patents in foreign jurisdictions, related to our DLL4/VEGF antibody program including, but not limited to, our tovecimig therapeutic candidate. Patents in these patent families are generally expected to start to expire in 2033, subject to possible extension.

We own 4 pending patent families with 11 issued U.S. patents and issued patents in Taiwan, China, Eurasia, Japan, Korea, Malaysia, Singapore, and New Zealand, 3 U.S. patent applications, and 39 patent applications in foreign jurisdictions, 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 1 pending patent family with 2 issued U.S. patents, issued patents in China, Japan, and Taiwan, 1 U.S. patent application, and 20 patent applications in foreign jurisdictions, 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, or have an ownership interest in, 2 pending patent families with 2 U.S. pending patent applications and 3 patent applications in foreign jurisdictions, related to our CD277 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 1 pending patent family with 1 U.S. pending patent application and 1 patent application in foreign jurisdictions related to our antibody and display programs including, but not limited to, common light chains. Patents that grant from this patent family 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 multiple jurisdictions for the COMPASS THERAPEUTICS word mark and logo for goods and services. We have filed for and obtained trademark protection on the StitchMabs™ word mark in the United States for 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 tovecimig, CTX-471, CTX-8371, CTX-10726 and our platform technologies, including our StitchMabs™ platform and our 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, Eli Lilly, Genentech, Inc., GlaxoSmithKline PLC, Johnson & Johnson, Merck & Co., Inc., Merck KGaA, Novartis AG, Pfizer Inc., Roche Holding Ltd and Sanofi S.A. Moreover, we may also compete with smaller or earlier-stage companies, universities and other research institutions that have developed, are developing or may be developing current and future cancer therapeutics.

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

Biliary tract cancers are aggressive and rare gastrointestinal cancers that have a very poor prognosis. First line treatment of locally advanced or metastatic BTC includes the chemotherapy combination of gemcitabine and cisplatin, often with the addition of the PD-1 inhibitor Imfinzi® (durvalumab). In September of 2022, AstraZeneca received FDA approval of durvalumab in combination with gemcitabine/cisplatin for the first line treatment of BTC. In addition, Merck received FDA approval of pembrolizumab in combination with gemcitabine/cisplatin for the first line treatment of BTC in October of 2023. The only FDA approved therapies for second line treatment of BTC are targeted therapies that address specific tumor mutations or solid tumors that are microsatellite instability high. For example, in November 2024, Jazz Pharmaceuticals received FDA approval of ziihera for previously treated, unresectable, or metastatic human epidermal growth factor receptor ("Her-2") positive biliary tract cancer, which may be beneficial to the small subset of patients in whom Her-2 is amplified. We believe that the combination of all targeted therapies are appropriately 10-15% of BTC patients.

Colorectal cancer is the second most common cause of cancer deaths in the United States and constitutes approximately 10% of all annually diagnosed cancer and cancer related deaths globally. Treatment of metastatic disease in the first line typically includes either the VEGF inhibitor Avastin® (bevacizumab) or an EGFR inhibitor such as Erbitux® (cetuximab), combined with chemotherapy. Treatment in the second line includes re-treatment with either a VEGR or EGFR inhibitor and a different chemotherapy regimen that is either oxaliplatin or irinotecan based. Approved therapies for advanced patients with metastatic disease are limited, with approved agents such as Lonsurf® (trifluridine and tipiracil) and Stivarga® (regorafenib) offering only 1-2% response rates and improvement in survival of 1-2 months.

If we are successful in advancing one or more of our product candidates toward registrational trials 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 (with the exception of limited countries for tovecimig), 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 trials, 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, 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 ("FDCA"), and the Public Health Service Act ("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 ("GLP"), regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent institutional review board ("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 ("GCPs"), to establish the safety and efficacy of the product candidate for each proposed indication;
- preparation of and submission to the FDA of a 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 ("cGMP");

- satisfactory completion of any FDA audits of the clinical trial 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.

Before testing any drug or biologic in humans, a product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of product chemistry, formulation, and stability, as well as in vitro and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulation and requirements, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND.

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 trial participants. The IND also includes results of animal and in vitro studies assessing the toxicology, PK, 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 trial, 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 trials 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 trials are typically referred to as Phase 4 clinical trials.

In March 2022, the FDA released a final guidance titled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," which outlines how drug developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology drug development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts is included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to drug development and reduce development costs and time.

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 and safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

A sponsor 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.

Concurrent with clinical trials, sponsors usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality, and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

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 2025, the user fee for an application requiring clinical data is $4,310,002, and the sponsor of an approved BLA is also subject to an annual program fee of $403,889 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 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 ("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.

Additionally, the FDA may grant a product candidate priority review designation, which sets the target date for FDA action on the marketing application for a novel product at six months after the FDA accepts the application for filing. Priority review is granted where the proposed product is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. 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 for a product that is intended to treat a serious or life-threatening disease or condition upon the determination that the product generally provides meaningful therapeutic benefit to patients over available treatments and demonstrates an effect on 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. Accelerated approval is usually contingent on a sponsor's agreement to conduct post-approval confirmatory trials or complete ongoing trials in a diligent manner to verify the product's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is now permitted to require, as appropriate, that post-approval confirmatory trials be underway prior to approval or within a specific time period after accelerated approval is granted and the FDA has increased authority for expedited procedures to withdraw approval of a product or an indication approved under accelerated approval if, for example, the confirmatory trial is not conducted with due diligence or fails to verify the predicted clinical benefit of the product. Additionally, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for preapproval and pre-use review.

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 or biological products, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the product candidate 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.

Finally, with respect to oncology products, the FDA may review applications under Real-Time Oncology Review ("RTOR") established by the FDA's Oncology Center of Excellence. RTOR allows an applicant to pre-submit components of the application to allow the FDA to review clinical data before the complete filing is submitted in order to create more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. Drugs considered for review under RTOR must, among other things, be likely to demonstrate substantial improvements on a clinically relevant endpoint(s) over available therapy and must have easily interpreted endpoints. In addition, no aspect of the application should be likely to require a longer review time (for example, a Risk Evaluation and Mitigation Strategy). To determine eligibility for RTOR, the FDA requires top-line efficacy and safety results from an applicant.

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. Manufacturers and manufacturers' facilities are also required to comply with applicable product tracking and tracing requirements and notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

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

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

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

Pediatric Trials and Exclusivity

A sponsor who is planning to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan ("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 for a biologic, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity for all formulations, dosage forms, and indications of the biologic, 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, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining. 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 ("Affordable Care Act"), signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCI"), which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the PHSA attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the proposed biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of its product. In addition, The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. The first biologic submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product is eligible for a period of exclusivity against other biologics submitted under the abbreviated approval pathway during which time the FDA may not determine that another product is interchangeable with the same reference product for any condition of use. The FDA may approve multiple "first" interchangeable products so long as they are all approved on the same first day of marketing. This exclusivity period, which may be shared amongst multiple first interchangeable products, lasts for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologic's patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period. Products deemed "interchangeable" by the FDA may be readily substituted by pharmacies and such substitution is which are governed by state pharmacy law.

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. 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 a 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.

Clinical Trial Approval in the European Union

In April 2014, the European Union adopted the Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022. The Clinical Trials Regulation is directly applicable in all European Union Member States meaning no national implementing legislation in each European Union Member State is required. The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial is required to submit a single application for approval of a clinical trial to a reporting European Union Member State centralized portal known as the Clinical Trials Information System. The submission procedure is the same irrespective of whether the clinical trial is to be conducted in a single European Union Member State or in more than one European Union Member State.

Marketing Authorization Procedures in the European Union

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

Centralized procedure. The European Medicines Agency ("EMA"), implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Economic Area ("EEA"), which is comprised of the Member States of the European Union plus Norway, Iceland, and Lichtenstein. This procedure results in a single marketing authorization issued by the EMA that is valid across the EEA. The centralized procedure is compulsory for human medicines that: are derived from biotechnology processes, such as genetic engineering; contain a new active substance indicated for the treatment of certain diseases, such as HIV, AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions; are advanced therapy medicines (gene-therapy, somatic cell-therapy or tissue-engineered medicines); and are 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, 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 in the European Union.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use ("CHMP") is responsible for conducting the initial assessment of a product and for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. 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 CHMP). Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. 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, the EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops, but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

National authorization procedures. There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for 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 Member State of medicinal products that have not yet been authorized in any European Union Member State 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 Member State. Following this, further marketing authorizations can be sought from other European Union Member States in a procedure whereby the Member State concerned agree to recognize the validity of the original, national marketing authorization.

Companies applying for a marketing authorization in the Europea Union must also agree upon a pediatric investigation plan ("PIP") with the EMA's Pediatric Committee and must conduct pediatric clinical trials in accordance with that PIP unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP.

Data and Market Exclusivity in the European Union

In the European Union, innovative medicinal products approved on the basis of a complete and independent data package 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 pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union, during a period of eight years from the date on which the reference product was first authorized in the European Union. During an additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted and authorized, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be placed on the European Union market until the expiration of the market exclusivity. 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. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained a marketing authorization based on a marketing authorization application with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

All of the aforementioned European Union rules are generally applicable in the EEA.

Reform of the Regulatory Framework in the European Union

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the European Union for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval and, in April 2024, the European Parliament proposed amendments to the legislative proposals. Once the European Commission's legislative proposals are approved (with or without amendment), they will be adopted into EU law. In October 2023, the European Parliament published draft reports proposing amendments to the legislative proposals, which will be debated by the European Parliament. Once the European Commission's legislative proposals are approved (with or without amendment), they will be adopted into European Union law.

Pharmaceutical Coverage, Pricing and Reimbursement

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

In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("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, 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.

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, 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 European Union 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 European Union 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 ("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 ("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, 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 70% 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.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- On August 2, 2011, the U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which will remain in effect through 2031.
- On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

- On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap, set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

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, President Trump reversed some of President Biden's executive orders including rescinding Executive Order 14087 titled "Lowering Prescription Drug Costs for Americans." President Trump may issue new executive orders designed to impact drug pricing. A number of these and other proposed measures may require authorization through additional legislation to become effective. Congress and the Trump administration have indicated that they will continue to seek new legislative measures to control drug costs.

In August 2022, the IRA was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effect of IRA on our business and the healthcare industry in general is not yet known.

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.

Other Healthcare Laws and Compliance Requirements

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, among others:

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

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

- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; 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 ("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.

Employees and Human Capital

As of December 31, 2024, we had 35 employees, 22 of which were primarily engaged in research and development and clinical activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

As an emerging company operating in a competitive industry, much of our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels and continue to focus on extending our diversity and inclusion initiatives across our entire workforce, from working with managers to develop strategies for building diverse teams to promoting the advancement of leaders from different backgrounds.

Corporate Information

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

Our principal executive offices are located at 80 Guest Street, Suite 601, Boston, Massachusetts 02135, and our telephone number is (617) 500-8099.

Our website is www.compasstherapeutics.com. Our 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. The SEC maintains a website that contains proxy 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.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below together with all of the other information in this Annual Report on Form 10-K ("Form 10-K"), including our financial statements and the related notes and the information described in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our other filings with the SEC. If any of the events described below actually occurs, our business, results of operations, financial conditions, cash flows or prospects could be harmed. If that were to happen, you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business.

Risks Related to Our Financial Position and Need for Additional Capital

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

We are a clinical-stage biopharmaceutical company with a limited operating history. Since our founding in 2014, we have incurred significant net losses with an accumulated deficit of $365 million as of December 31, 2024. We have funded our operations to date primarily with proceeds from private placements of preferred and common equity, an underwritten public offering and a PIPE offering, as well as sales under our at-the-market offering program pursuant to an Open Market Sale Agreement℠ with Jefferies LLC. 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, including clinical development, 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, including our proprietary StitchMabs™ technology, to advance additional product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality control, regulatory, scientific and administrative personnel;
- expand our operational, financial and management systems and increase personnel, including to support our clinical development and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio;
- establish a marketing, sales, distribution and medical affairs infrastructure to commercialize any products for which we may obtain marketing approval and commercialize, whether on our own or jointly with a partner;
- acquire or in-license other technologies or engage in strategic partnerships; and

- incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company.

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

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

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

- completing preclinical studies and clinical trials of our product candidates;
- 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. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

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

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our current and future programs. If we receive marketing approval for any product candidates, 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 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 our product candidates, and of conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approval for any of our current or future product candidates we develop, if clinical trials are successful;
- the costs of manufacturing our current and any future product candidates for preclinical studies and clinical trials and in preparation for marketing approval and commercialization;
- the costs of commercialization activities, including marketing, sales and distribution costs, for our products 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 December 31, 2024, we had $126.7 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 2027. 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, investors' 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.

Recent volatility in capital markets and lower market prices for our securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may harm our liquidity and limit our ability to grow our business, pursue acquisitions, or improve our operating infrastructure.

Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, respond to business challenges or opportunities, develop our product candidates, retain or expand our current levels of personnel, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements;
- develop our product candidates;
- pursue acquisitions or other strategic relationships; and
- respond to competitive pressures.

Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our business.

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. 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 our current products or future product candidates we develop, which may never occur. Our current product candidates 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 new INDs with the FDA for our current and future product candidates;
- our ability to complete preclinical studies for current or future product candidates;
- successful enrollment in, and completion of clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- our ability to establish agreements with third-party manufacturers on a timely and cost-efficient manner;
- whether we are required by the FDA or comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned or anticipated to support approval of our product candidates;
- acceptance of our proposed indications and the primary endpoint assessments evaluated in the clinical trials of our product candidates by the FDA and comparable foreign regulatory authorities;
- receipt and maintenance of timely marketing approvals from applicable regulatory authorities;
- successfully launching commercial sales of our product candidates, if approved;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if approved;

- entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- acceptance of the benefits and uses of our product candidates, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety, tolerability and efficacy profile of the product candidates following approval;
- our compliance with any post-approval requirements imposed on our products, such as post-marketing studies, 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; 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 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.

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

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe, pure and potent in humans. Clinical testing is expensive and can take many years to complete, and its outcome is highly uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials. We cannot be certain the ongoing and planned preclinical studies or clinical trials for our current or any other 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 ("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 ("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;
- enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or may fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our CROs and other third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;
- any of our product candidates could cause undesirable side effects that could result in significant negative consequences, including the inability to enter clinical development or receive regulatory approval;
- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;
- we may face hurdles in addressing subject safety concerns that arise during the course of a trial, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate trials, or reports may arise from nonclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates;

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

- we may need to change the manufacturing site and potentially the contract development manufacturing organizations ("CDMO") 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 and Safety Monitoring Board ("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 additional "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 trials 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, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down the development and approval process for our product candidates and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates.

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

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

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.

The risk of failure for product candidates still in the discovery or preclinical stage is high. In addition, any one or more of our product candidates that have not yet entered the clinic may never advance into clinical development. In order to obtain FDA approval to market a new biologic we must demonstrate proof of safety, purity and potency, including efficacy, in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned clinical trials in humans. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our current or future product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

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

- an inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory agencies on trial design; 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 PK and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules, and the results of any early-stage clinical trials may not be predictive of the results of later-stage, large-scale efficacy clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs and biological products proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

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

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

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

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

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

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

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

Immuno-oncology drugs have been observed to cause side effects, generally related to over activation of the immune system. These include colitis, diabetes, pituitary inflammation, thyroiditis, myocarditis, liver inflammation, thrombocytopenia, among others. Our immuno-oncology product candidates may have similar or additional side effects. Treatment-related side effects may emerge at a later time in our trials. 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. There can be no assurance that any of our current or future product candidates 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 trials are conducted or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Although our current and future product candidates have undergone and will undergo safety testing to the extent possible and, where applicable, under such conditions discussed with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated. Antibody therapeutics and bispecifics and their method of action of harnessing the body's immune system are powerful and could lead to serious side effects that we only discover in clinical trials or during commercial marketing. Unforeseen side effects could arise either during clinical development or after our product candidates have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients. So far, we have not demonstrated that our current product candidates are 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 our product candidates in combination with other therapies and may develop 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 our product candidates through clinical trials, such trials will likely only include a limited number of subjects and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trial may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period.

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

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

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

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

The design and implementation of clinical trials is a complex process. We have limited experience designing and implementing clinical trials, and we may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the trial 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 our current product candidates 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 for our current product candidates 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 our 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; and

- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our current and potential future product candidates. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such sites. Moreover, because our current and potential future product candidates may represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in our ongoing or any future clinical trial.

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

Because the number of subjects in our clinical trials are small, the results from these trials, once completed, may be less reliable than results achieved in larger clinical trials.

A trial 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 trials with smaller sample sizes and heterogeneous patient populations, 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 trial results less reliable than trials with a larger number of subjects and with more homogeneous patient populations. As a result, there may be less certainty that our product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials, we may not achieve a statistically significant result or the same level of statistical significance seen, if any, in our clinical trials.

We have chosen to prioritize certain product candidates for development as described in this Annual Report on Form 10-K. 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 certain product candidates as described in this Annual Report on Form 10-K, rather than other product candidates. This decision is based, in part, on the significant resources required for developing and manufacturing antibody therapeutics and bispecifics. 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.

Our clinical trials may be conducted in overseas jurisdictions, which may subject us to delays and expenses.

We may conduct certain clinical trials in overseas jurisdictions. Regulators in the United States, such as the FDA, or in other foreign jurisdictions, may not support our trial design and protocol, which would delay our clinical development plans and increase our expenses.

In addition, there are risks inherent in conducting clinical trials in overseas jurisdictions, which may subject us to delays and expenses, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct clinical trials;
- differing and conflicting regulatory requirements;
- foreign exchange fluctuations; manufacturing, customs, shipment, and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

Risks Related to Regulatory Approval of Our Product Candidates

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 ("BLA"), from the FDA. It is possible that none of our current or future product candidates will ever obtain regulatory approval from the FDA or comparable foreign regulatory authorities.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate has an acceptable risk-benefit profile in the proposed indication;

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that the facility in which a product candidate is manufactured meets standards designed to assure that the product candidate continues to be safe, pure, and potent;

- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA or regulatory submissions to comparable regulatory authorities to obtain regulatory approval in such jurisdiction; and

- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve our manufacturing processes or facility or the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.

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

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

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

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

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

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

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

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

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

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

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

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. Currently, federal agencies in the United States are operating under a continuing resolution that is set to expire on March 14, 2025. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted.

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 ("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 trial 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 trial protocols;
- deficiencies in the clinical trial operations or trial sites;
- unforeseen adverse side effects or the emergence of undue risks to trial 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 intend to develop our product candidates in part in combination with other therapies and may develop our future product candidates in combination with other therapies, which exposes us to additional regulatory risks.

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

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

We may also evaluate our current 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 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 any product candidate we develop, we may be unable to obtain approval of or market any such product candidate.

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, tracking and tracing event and deviation reporting, storage, advertising, promotion, import and export and record keeping for the product candidate will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and cGCP, for any clinical trials that we may conduct post-approval. Later discovery of previously unknown problems with any approved candidate, including adverse events of unanticipated severity or frequency, or with our or our third-party manufacturers' manufacturing processes or facilities, or failure to comply with regulatory requirements, may result in, among other things:

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

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

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

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

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

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.

Accelerated approval by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive regulatory approval.

We may seek accelerated approval of our current or future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition. In addition, it must demonstrate an effect on 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 ("IMM"), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing confirmatory clinical trials. These confirmatory trials must be completed with due diligence. Under the FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-marketing confirmatory trial or submit timely reports to the agency on their progress. In addition, the FDA currently requires, unless otherwise informed by the agency, as a condition for accelerated approval pre-approval of promotional materials for products being considered for accelerated approval, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development, regulatory review or approval process, and receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

Risks Related to the Commercialization of Our Product Candidates

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. In addition, adverse events in clinical trials testing our product candidates or in clinical trials of others developing similar product candidates and the resulting publicity, as well as any other adverse events in the field of immuno-oncology that may occur in the future, could result in a decrease in demand for our current or future product candidates. Furthermore, to date, only a few bispecific products have received marketing approval and only a few have advanced to late-stage clinical development. Future adverse events in immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Similarly, the use of agonist antibodies for the treatment of autoimmune diseases is novel and there can be no assurance that our product candidates for the treatment of autoimmune diseases, if approved, would gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community.

If our current and any future product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our current and any future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments, including those that are not yet approved;
- the ability to offer our products, if approved, for sale at competitive prices;

- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing, sales and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy; and
- the prevalence and severity of any side effects.

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

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

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

We may initially seek approval for 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.

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.

If we are unable to establish marketing, sales and distribution capabilities for any 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 any product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own marketing, sales and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

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

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

Risks Related to Healthcare, Insurance and Legal Matters

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.

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

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. The availability of coverage and adequacy of reimbursement by third-party payors, including government healthcare programs (e.g., Medicare, Medicaid), managed care providers, private health insurers, health maintenance organizations, and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. Third-party payors decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and other third-party payors is essential for most patients to be able to afford treatments such as antibody-based therapies. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("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. See the section entitled, “Business — Government Regulation — Pharmaceutical Coverage, Pricing and Reimbursement”.

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. 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.

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.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. See the section titled, "Business — Government Regulation — Current and future healthcare reform legislation".

Moreover, increasing efforts by governmental and other 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. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been 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, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

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. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our approved products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

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. See the section titled, "Business — Government Regulation — Other Healthcare Laws and Compliance Requirements".

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.

Risks Related to Manufacturing of Our Product Candidates

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 CDMOs, to manufacture our product candidates for preclinical and clinical trials. If approved, commercial supply of any product candidates may also be manufactured at one or more CDMOs.

The facilities used by our CDMOs 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 CDMOs and are completely dependent on them for compliance with current regulatory requirements. If we or our CDMO 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 CDMOs 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 CDMOs 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 CDMOs 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. If our CDMOs 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 CDMO for manufacturing any of our product candidates to one that can support commercial-scale manufacturing. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

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

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

- product loss during the manufacturing process, including loss caused by contamination, equipment failure or improper installation or operation of equipment, or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;

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

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

- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

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

Risks Related to Intellectual Property

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

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

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

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

We may not be aware of all third-party intellectual property rights potentially relating to our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, only upon issuance or not at all. Therefore, we cannot be certain that we, or a licensor, were the first to make the inventions claimed in any owned or any licensed patents or pending patent applications, respectively, or which entity was the first to file for patent protection until such patent application publishes or issues as a patent. Databases for patents and publications, and methods for searching them, are inherently limited, so it is not practical to review and know the full scope of all issued and pending patent applications. As a result, the issuance, scope, validity, enforceability, and commercial value of our and our licensed patent rights are uncertain. Furthermore, if third parties have filed such patent applications, we may challenge their ownership, for example in a derivation proceeding before the U.S. Patent and Trademark Office ("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 third party payment services 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 then-President Trump on March 19, 2018. The Executive Order banned transactions involving "any digital currency, digital coin, or digital token, that was issued by, for, or on behalf of the Government of Venezuela on or after January 9, 2018." The prohibition is applicable to any U.S. entity unless exempted by license. We do not hold such a license and therefore may not be able to secure patents in Venezuela. A presidential decree dated January 14, 2020 formally established the PETRO as a mandatory means of payment. In response, the Venezuelan Patent Office established an alternative payment method allowing the receipt of deposits with the value of corresponding Official fees in U.S. Dollars and Euros in cash at a non-sanctioned governmental bank. While this has been an adequate course of action to proceed in compliance, there is no guarantee it will remain so.

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

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

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

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

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

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

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

Depending upon the timing, duration and specifics of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 ("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 or more than five years beyond the patent's natural expiration date, 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 ("the America Invents Act"), the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention.

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

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

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

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

Competitors may infringe our patents or the patents of our licensors, or we may be required to defend against claims of infringement. Countering infringement or unauthorized use claims or defending against claims of infringement can be expensive and time-consuming. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future marketing, sales or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

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

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect, and some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license or may own in the future;
- we, or any partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or any partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;

- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to Information Technology and Data Privacy

We depend on our information technology systems, and any failure of these systems could harm our business. Cybersecurity incidents, data 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.

We, like other organizations in our industry, may experience cybersecurity incidents. The risk of cybersecurity incidents, data breaches 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 impacted stakeholders (including affected individuals, regulators and investors pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, as amended ("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. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations.

We are or may become subject to other U.S. federal and state laws governing the privacy and security of health information, many of which differ from each other in significant ways and may not be preempted by HIPAA. For example, the California Consumer Privacy Act (CCPA) created individual privacy rights for California residents, including requiring covered businesses to provide notice regarding how personal information is collected and how individuals can limit the sharing of their personal information. The California Privacy Rights Act (CPRA) amended the CCPA and requires specific disclosures and safeguarding requirements around sensitive personal information. The CPRA also establishes a state agency vested with the authority to enforce the CCPA. The CCPA also applies to personal information collected about employees, applicants and retirees, as well as that which is collected in a business-to-business capacity. While there is currently an exception in the CCPA for protected health information that is subject to HIPAA, the CCPA may nevertheless impact our data use and sharing practices and require significant investment in our effort to comply with its obligations.

More than a dozen other U.S. states have enacted legislation similar to the CCPA, but contain key differences in their scope, application, and enforcement. Clear enforcement guidelines, as well as associated penalties for noncompliance, are likely to be unpredictable for the foreseeable future. Moreover, certain states have advanced privacy laws focused on protecting consumer health information, such as Washington's My Health My Data Act, which contains a private right of action and my increase the risk of litigation. and this remains a rapidly changing legislative and regulatory environment. Any actual or perceived noncompliance with privacy and data protection laws by us or our partners may damage to our reputation, lead to loss of existing or future business, require us to change our data practices and increase our expenses related to litigation and compliance ongoing compliance, any of which could adversely affect our business, results of operations and financial condition.

In December 2024, the U.S. Department of Justice issued regulations implementing Executive Order ("EO") 14117, "Preventing Access to Americans' Bulk Sensitive Personal Data and United Stated Government-Related Data by Countries of Concern," which are expected to become effective in April 2025. These regulations prohibit transactions involving access to bulk sensitive data by countries of concern, such as China (including Hong Kong). In the life sciences sector, the regulations prohibit investment agreements, employment agreements, vendor agreements, and other transactions involving human genomic data and biospecimens, except where necessary for specified exempt activities. Tracking and complying with these regulations may require significant time and expense.

Our use of new and evolving technologies, such as artificial intelligence, may present risks and challenges that can impact our business, including by posing cybersecurity and other risks to our confidential and/or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability.

We may use and integrate artificial intelligence into our business processes. Use of this rapidly evolving technology will require the application of significant resources to design, develop, test, and maintain such systems to help ensure that artificial intelligence is implemented in accordance with applicable law and in a socially responsible manner. If we enable or use solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm, or legal liability.

A growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of artificial intelligence, and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of artificial intelligence and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, the EU's Artificial Intelligence Act ("AI Act") entered into force on August 1, 2024, with most provisions becoming effective on August 2, 2026. This legislation imposes significant obligations on providers and deployers of artificial intelligence systems and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. The scope of requirements depends on legal and risk determinations that rely on novel legal provisions that have not yet been interpreted by courts or regulators, and non-compliance can lead to significant fines.

Likewise, in the U.S., several states, including Colorado and California, passed laws that will take effect in 2026, to regulate various uses of artificial intelligence, including to make consequential decisions. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. If we develop or use AI systems governed by these laws or regulations, we will need to meet higher standards of data quality, transparency, monitoring, and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non-compliance.

Our vendors may in turn incorporate artificial intelligence tools into their offerings, and the providers of these artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, global threat actors are using increasingly sophisticated methods, including artificial intelligence, to engage in the theft and misuse of confidential information and proprietary information. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

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 in the EEA or the UK or enroll subjects residing in the EEA or the UK 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 EEA, including personal health data, is subject to the EU General Data Protection Regulation ("EU GDPR"). EU GDPR has been incorporated into U.K. domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018 and amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 ("U.K. GDPR", together with the EU GDPR referred to as "GDPR"). The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to the processing of sensitive data (such as health data), obtaining consent of the individuals to whom the personal data relates or ensuring another legal basis or condition applies to the processing of personal data, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, where required providing notification of data breaches, requiring data protection impact assessments for high risk processing 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 or the U.K. (see below), 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 (£17.5 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.

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. The U.K. plans to reform the country's data protection legal framework in its Data Use and Access Bill, which was introduced into the U.K. legislative process on October 23, 2024 and, if passed, will introduce significant changes. This may lead to additional compliance costs and could increase our overall risk exposure as we may no longer be able to take a unified approach across the EU and the U.K.

The GDPR includes restrictions on cross-border data transfers. Adequate safeguards must be implemented to enable the transfer of personal data outside of the EEA or the U.K., in particular to the U.S., in compliance with European and U.K. data protection laws. On June 4, 2021, the European Commission ("EC") issued new forms of standard contractual clauses for data transfers from controllers or processors in the EEA (or otherwise subject to the EU GDPR) to controllers or processors established outside the EEA (and not subject to the EU GDPR). The U.K. is not subject to the EC's new standard contractual clauses but has published its own version of standard clauses, referred to as "International Data Transfer Agreement" which entered into force on 21 March 2022 and enables transfers originating from the U.K. The U.K. Government has confirmed that transfers from the U.K. to the EEA may currently continue to flow freely. Transfers made pursuant to these new mechanisms need to be assessed on a case-by-case basis to ensure the law in the recipient country provides "essentially equivalent" protections to safeguard the transferred personal data as the EU, and businesses are required to adopt supplementary measures if such standard is not met. Further, the EU has adopted its adequacy decision for the EU-U.S. Data Privacy Framework ("Framework"), which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred from the EU to companies which are certified to the Framework in the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover U.K. transfers to the United States. The Framework could be challenged like its predecessor frameworks. We will be required to implement these new safeguards when conducting restricted data transfers under the GDPR and doing so will require significant effort and cost.

The use of new and evolving technologies, such as artificial intelligence, in our business may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential and/or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability.

Risks Related to Our Work with Third Parties

We rely or will rely on third parties to help conduct our ongoing and planned preclinical studies and clinical trials for our current product candidates 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 our current product candidates 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 ("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, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GLP and cGCP, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

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

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

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation or that could jeopardize or invalidate our intellectual property or proprietary information, exposing us to potential litigation or other intellectual property proceedings;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new product candidates.

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

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

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

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

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

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Such exclusivity could limit our ability to enter into strategic collaborations with future collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any marketing or sales activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Our Business

We 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, in the case of drugs, have a better safety profile than our product candidates. These competitors may also be more successful than us in manufacturing and marketing their products, and have significantly greater financial resources and expertise in research and development.

There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. Currently marketed oncology drugs and therapeutics range from traditional cancer therapies, including chemotherapy, to antibody-drug conjugates, such as Genentech's Kadcyla, to immune checkpoint inhibitors targeting CTLA-4, such as BMS' Yervoy, and PD-1/PD-L1, such as BMS' Opdivo, Merck & Co.'s Keytruda and Genentech's Tecentriq, to T cell-engager antibody therapeutics, such as Amgen's Blincyto. In addition, numerous compounds are in clinical development for cancer treatment. Many of these companies are well-capitalized and have significant clinical experience.

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

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

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

As our development plans and strategies develop, and as we continue 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 our current product candidates 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 our current product candidates 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 our current product candidates and any current or future product candidates we develop and, accordingly, may not achieve our research, development and commercialization goals.

We have broad discretion in the use of our cash resources and may not use them effectively.

We currently intend to use our cash resources for clinical development of our product candidates, the advancement of our preclinical and discovery programs in development, and for working capital and other general corporate purposes. Although we currently intend to use our cash resources in such a manner, we will have broad discretion in their application. 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.

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 could leave our employment at any time, as all of our employees are "at-will" employees. The loss of the services of these officers could impede the achievement of our research, development and commercialization objectives.

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

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to annually report upon the effectiveness of our internal control over financial reporting. When we lose our status as an "emerging growth company" and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. As we grow, we expect to hire additional personnel and may utilize external temporary resources to implement, document and modify policies and procedures to maintain effective internal controls. However, it is possible that we may identify significant deficiencies and/or material weaknesses in our internal controls. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Although we have determined that our internal control over financial reporting was effective as of December 31, 2024, we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our business, results of operations and future growth prospects could be or continue to be affected by global pandemics, such as the COVID-19 pandemic, or the future outbreak of other highly infectious or contagious diseases.

Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business activities and could cause significant disruption in the operations of third-parties on which we rely. We cannot precisely determine or quantify the impact the future outbreak of any highly infectious our contagious diseases, such as the COVID-19 pandemic, will have on our business operations in the future, which 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 United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and the pandemic.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under current law, unused federal net operating losses generated for tax years beginning after December 31, 2017 are not subject to expiration and may be carried forward indefinitely. For taxable years beginning after December 31, 2020, the deductibility of such federal net operating losses is limited to 80% of our taxable income in any future taxable year. In addition, in general, under Sections 382 and 383 of the Code, a corporation that undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership by certain stockholders over a three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses and research and development tax credit carryforwards to offset future taxable income. We may have experienced such ownership changes in the past and may experience such ownership changes in the future (which may be outside our control). As a result, if, and to the extent that, we earn net taxable income, our ability to use our pre-change net operating losses and research and development tax credit carryforwards to offset such taxable income may be subject to limitations.

Risks Related to Our Common Stock

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 December 31, 2024, our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned approximately 30% of our common stock. 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.

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.

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

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

Our amended and restated bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a 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 form time to time) or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein; provided, however, that this exclusive forum provision will not apply to any causes of action arising under the Securities Act of 1933, as amended ("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 Boston, 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, 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.

General Risk Factors

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

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

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

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

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

We will continue to incur increased costs as a result of being a public company and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act ("the Dodd-Frank Act"), was enacted. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business. For example, we expect that these rules and regulations may make it more difficult and 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 maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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 and smaller reporting companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("the Sarbanes-Oxley Act"), reduced disclosure obligations regarding executive compensation in our registration statements, if applicable, and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement, (ii) the last day of the first fiscal year in which we have total annual gross revenues of at least $1.235 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 million, 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.

Even after we no longer qualify as an "emerging growth company," we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the independent auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. 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 share 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.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a "smaller reporting company" until (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million as of the prior June 30. If we are a "smaller reporting company" at the time we cease to be an "emerging growth company," we may continue to rely on exemptions from certain disclosure requirements that are available to "smaller reporting companies." Specifically, as a "smaller reporting company" we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, "smaller reporting companies" have reduced disclosure obligations regarding executive compensation.

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

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

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

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

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

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

- results of clinical trials of our product candidates;
- the timing of the release of results of our clinical trials;
- results of clinical trials of our competitors' products;
- safety issues with respect to our products or our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;

- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us, our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biopharmaceutical stocks; and
- changes in general market and economic conditions.

In addition, the 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.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

We recognize the importance of safeguarding the security of our computer systems, software, networks, and other technology assets. We have implemented and maintain a security risk management program that is designed to preserve the confidentiality, integrity, and continued availability of information under our ownership or care with the aim to continually improve security features in order to keep pace with the evolving cyber threat landscape.

We face a number of cybersecurity risks in connection with our business and recognize the growing threat within the general marketplace and our industry. Although such risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we and our vendors have, from time to time, experienced threats to and breaches of our data and systems. For more information about the cybersecurity risks we face, see the section titled "Risk Factors — Risks Related to Information Technology and Data Privacy".

Risk Management and Strategy

We have implemented internal controls including regular risk assessments designed to address financial, operational and information technology (including cybersecurity) risks and controls across our organization. These assessments are overseen by our Director of IT and Chief Accounting Officer. We implement cybersecurity controls and procedures designed to address cyber risks and threats, supported by third-party technologies and security advisors and providers. We also provide cybersecurity awareness training to our employees during the onboarding process and periodically thereafter. In addition, we engage external third-party information security consultants to periodically conduct information security testing and assessments, and to evaluate our overarching information security program and specific incident response procedures. We also maintain a Cyber Incident Response Plan, which is overseen by our Director of IT and is designed to coordinate our response to information security incidents. Finally, we hold and maintain third-party insurance coverage for cybersecurity risks commensurate with industry standards for a company of our size and stage.

Cybersecurity Oversight

The Director of IT is responsible for implementing and maintaining the information security program. The Director of IT role is currently held by an individual who has more than 20 years of professional IT management experience and maintains a Global Information Assurance Certification. The Director of IT reports to our Chief Accounting Officer, who together are responsible for coordinating information security risk assessments and overseeing periodic testing of our cybersecurity controls. Our Chief Accounting Officer meets with the audit committee of our board of directors periodically for the audit committee to provide guidance on the prioritization of the risk remediation and ongoing implementation of cybersecurity improvements across our organization. We also engage an external auditing firm with information security expertise to conduct regular auditing, testing, and review of our information technology risks, processes, and operations.

Management also generally provides quarterly updates to the audit committee on cybersecurity and other information technology risks. We have implemented a process for the Director of IT and the Chief Accounting Officer to receive incident reports and report quarterly (and, if applicable, in the event of a cybersecurity incident), to our internal disclosure committee and the audit committee, as appropriate. Management presents to the entire board of directors on an annual basis, including any key findings identified in our cybersecurity assessments.

Item 2. Properties.

Our corporate headquarters is located at 80 Guest Street, Boston, Massachusetts, and consists of 19,112 square feet of office space and laboratory space pursuant to a sublease agreement that expires in May 2025. In September 2024, we signed a new lease on our existing facility, effective May 2025, extending the term six years to May 2031 and expanding the space to 29,836 square feet. 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.

Item 3. 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.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information and Holders of Record

On November 2, 2021, shares of our common stock were approved for trading on the Nasdaq Capital Market under the symbol "CMPX".

As of February 20, 2025, there were approximately 100 stockholders of record of our common stock. The actual number of stockholders is greater than this number and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividends

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.

Securities Authorized for Issuance under Equity Compensation Plans

Our 2020 Stock Option and Incentive Plan (the "2020 Plan") is the only equity incentive plan approved and adopted by our stockholders and provides for the issuance of shares of our common stock to our officers and other employees, directors and consultants.

The following table presents information as of December 31, 2024 with respect to compensation plans or arrangements under which shares of our common stock may be issued:

Plan category	Number of securities to be issued upon exercise of outstanding stock options, warrants and rights (000's)	Weighted-average exercise price of outstanding stock options, warrants and rights	Number of securities remaining available for issuance under equity compensation plans (000's)
Equity compensation plans approved by security holders	17,828(1)	$ 2.83(1)	1,418
Equity compensation plans not approved by security holders	—	—	—
Total	17,828	$ 2.83	1,418

(1) Includes 3.8 million shares of common stock issuable (subject to vesting) with respect to restricted stock units granted pursuant to the 2020 Plan; 675 thousand at a grant date fair market value of $3.93 per share, 300 thousand at a grant date fair market value of $3.83 per share, 400 thousand at a grant date fair market value of $1.65 per share and 2.4 million at a grant date fair market value of $1.93 per share. This value is not included in the weighted average exercise price.

On January 1, 2025, an additional 5.5 million shares became available for issuance for a total of 6.9 million shares available for future issuance. For further description of the equity compensation plans, see Note 9 to the consolidated financial statements included in this Annual Report on Form 10-K.

Item 6. [Reserved].

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Unless otherwise stated or the context otherwise indicates, references to the "Company", "we", "our", "us" or similar terms refer to Compass Therapeutics, Inc. together with its wholly-owned subsidiaries, which we refer to as Compass Therapeutics.

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 Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-K, 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 Form 10-K. You should review the disclosure under the heading "Risk Factors" in this Form 10-K 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, oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics to treat multiple human diseases. Our scientific focus is on the relationship between angiogenesis, the immune system, and tumor growth. Our pipeline of novel product candidates is designed to target multiple critical biological pathways required for an effective anti-tumor response. These include modulation of the microvasculature via angiogenesis-targeted agents, induction of a potent immune response via activators on effector cells in the tumor microenvironment, and alleviation of immunosuppressive mechanisms used by tumors to evade immune surveillance. We plan to advance our product candidates through clinical development as both standalone therapies and in combination with proprietary pipeline antibodies based on supportive clinical and nonclinical data.

Financial Overview

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. We have funded our operations primarily with proceeds from the sale of equity securities of $430 million through December 31, 2024.

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 $49.4 million and $42.5 million for the years ended December 31, 2024 and 2023, respectively, and as of December 31, 2024, we had an accumulated deficit of $365 million. 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.

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 December 31, 2024, we had $126.7 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 expenditures requirements into the first quarter of 2027. 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.

Listing on the Nasdaq Capital Market

On November 2, 2021, shares of our common stock were approved for trading on the Nasdaq Capital Market under the symbol "CMPX".

Private Investment in Public Entity ("PIPE") Offering

On November 2, 2023, we entered into a securities purchase agreement ("the "Securities Purchase Agreement") with certain accredited investors (the "Investors") pursuant to which we agreed to sell and issue to the Investors in a PIPE financing an aggregate of 25,000,000 shares of our common stock at a purchase price of $3.21 per share. The 25,000,000 shares were issued on November 4, 2023. The gross proceeds to us from the PIPE are $80.3 million (before deducting placement agent fees and other expenses in connection with the offering).

In connection with the PIPE offering, we paid $4.5 million to the underwriters and for other legal and accounting costs, for net proceeds of $75.8 million.

The PIPE offering was made pursuant to our registration statement on Form S-3 (File No. 333-268652), filed with the SEC on December 2, 2023, and declared effective by the SEC on January 20, 2024, including a prospectus thereto that was filed with the SEC on January 24, 2024.

The PIPE offering was exempt from registration under Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D promulgated by the SEC thereunder. The common stock in the PIPE offering was sold to "accredited investors", as defined in Regulation D.

At-The-Market ("ATM") Offering

In the first quarter of 2024, we sold, through our Open Market Sale Agreement℠ with Jefferies LLC, 9,790,577 shares of common stock at an average price of $1.85 for total proceeds of $18.1 million and net proceeds of $17.6 million.

In the second quarter of 2023, we sold, through our Open Market Sale Agreement℠ with Jefferies LLC, 951,873 shares of common stock at an average price of $3.28 for total proceeds of $3.1 million and net proceeds of $3.0 million.

Inflation Reduction Act of 2022

The Inflation Reduction Act of 2022 ("IRA") was enacted on August 16, 2022. The IRA includes provisions imposing a 1% excise tax on share repurchases that occur after December 31, 2022 and introduces a 15% corporate alternative minimum tax on adjusted financial statement income. To date, the IRA has not had a material impact on our consolidated financial statements.

Components of Results of Operations

Research and development

Research and development expenses consist primarily of costs incurred in connection with the development of our clinical product candidates, tovecimig, CTX-471 and CTX-8371, as well as unrelated preclinical and discovery program expenses. We expense research and development costs as incurred. These expenses include:

- development milestone payments due in connection with our product candidates;
- employee-related expenses, including salaries, related benefits and equity-based compensation expense, for employees engaged in research and development functions;
- Contract Research Organizations ("CROs") that are primarily engaged to support the clinical development of our product candidates;
- Contract Development Manufacturing Organizations ("CDMOs") that are primarily engaged to provide drug substance and drug 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;
- cost of acquiring and manufacturing nonclinical and clinical trial materials, including manufacturing registration and validation batches;
- costs related to compliance with quality and regulatory requirements; and
- payments made under third-party licensing agreements.

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

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

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

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the location where the trials are conducted;

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

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

- the timing and progress of nonclinical and clinical development activities;
- the number and scope of nonclinical and clinical programs we decide to pursue;
- raising necessary additional funds;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current development program and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of drug substance and drug product for use in production of our product candidate;
- establishing and maintaining agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidates are approved;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidate, if and when approved;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;

- the acceptance of our product candidate, if approved, by patients, the medical community and third-party payors;
- competition with other products; 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.

Other income

In 2024 and 2023, the only component of other income was interest income from marketable securities.

Income taxes

We are organized as a Delaware corporation and treated as a c-corporation for federal and state income taxes. Our wholly-owned subsidiaries are included in the consolidated corporate tax return. Prior to the Merger in 2020, we were established as a Delaware limited liability company, and the business that was acquired in the Merger was treated as a partnership for income tax reporting purposes; therefore, federal and state income taxes were the responsibility of its individual members. As such, no federal or state income taxes related to the limited liability company were recorded in our consolidated financial statements. All such taxes have been recorded in our financial statements. As of December 31, 2024 we recorded a deferred tax asset of $59.5 million primarily related to a net operating loss carryforward, section 174 capitalization, research and development tax credit carryforward, and capitalized licensing fees. The asset has a corresponding full deferred tax valuation allowance. Pursuant to Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in the ownership of its equity over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. See Note 13 to our consolidated financial statements appearing in this Form 10-K.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following table summarizes the results of operations for the years ended December 31, 2024 and 2023:

	Year Ended December 31,		
	2024	2023	Change
	(000's)		
Licensing revenue	$ 850	$ —	$ 850
Operating expenses:			
Research and development	42,342	38,120	4,222
General and administrative	15,133	12,243	2,890
Total operating expenses	57,475	50,363	7,112
Loss from operations	(56,625)	(50,363)	(7,112)
Other income	7,250	7,869	(619)
Net loss	$ (49,375)	$ (42,494)	$ (7,731)

Licensing revenue

Licensing revenue was $850 thousand for the year ended December 31, 2024. There was no licensing revenue for the year ended December 31, 2023. The licensing revenue consisted of a $1 million milestone payment from Elpiscience for completing a Phase 1 trial in China. This license revenue is reported net of a 15% sublicense royalty due ABL Bio (see Note 10 of the consolidated financial statements appearing in this Form 10-K for further information on this sublicense agreement).

Research and development expenses

Research and development expenses increased by $4.2 million from $38.1 million in 2023 to $42.3 million in 2024. This increase was primarily attributable to a $2.4 million increase in clinical and manufacturing costs related to our lead program, tovecimig, and $1.3 million from our second program, CTX-471, as described below.

We track supplies, outsourced development, personnel costs and other research and development costs of specific programs. Facility and equipment costs are not allocated to programs. Research and development expenses are summarized by program in the table below:

	Year Ended December 31,		
	2024	2023	Change
	(000's)		
CTX-009	$ 27,938	$ 25,558	$ 2,380
CTX-471	4,863	3,575	1,288
CTX-8371	3,473	3,964	(491)
Other research and development expenses	6,068	5,023	1,045
Total research and development expenses	$ 42,342	$ 38,120	$ 4,222

General and administrative expenses

General and administrative expenses increased by $2.9 million from $12.2 million in 2023 to $15.1 million in 2024. The increase was primarily attributable to higher personnel expense, including stock compensation of $2.3 million, driven by the CEO transition during the year. We anticipate that our general and administrative expenses will increase in the future as we expand our operations to support our growing research and development efforts, as well as potential commercial operations.

Other income

Other income consists only of interest income which decreased by $0.6 million from $7.9 million in 2023 to $7.3 million in 2024.

Income tax expense

We did not have income tax expense in 2024 or 2023.

Liquidity and Capital Resources

Since our inception, we have not 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. We have funded our operations primarily with proceeds from private placements of preferred and common equity and an underwritten public offering in the fourth quarter of 2021. Through December 31, 2024, we received gross proceeds of $430.5 million from the sale of equity securities, including $136.5 million in gross proceeds from our Follow-On Public Offering, $60.5 million in gross proceeds from the sale of our common stock in the Private Placement, $80.3 million in gross proceeds from a PIPE financing and $21.2 million in gross proceeds from sales through our ATM facility. As of December 31, 2024, we had cash, cash equivalents and marketable securities of $126.7 million.

On July 9, 2021, we filed an S-3 registration statement which became effective July 20, 2021. Included in this registration statement was a shelf registration allowing us to sell securities up to $300 million. The Follow-On Public Offering was made pursuant to this registration statement. In addition, the S-3 registration statement included a sales agreement with B. Riley Securities, Inc., pursuant to which we could offer and sell shares of our common stock having an aggregate of up to $75 million. We terminated the sales agreement with B. Riley effective July 29, 2022.

On August 1, 2022, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, pursuant to which we may offer and sell, from time to time at our sole discretion, shares of our common stock.

On December 2, 2022, we filed an S-3 registration statement which was declared effective by the SEC on January 20, 2023, for the shares issued through the PIPE offering.

On August 30, 2024, we filed an S-3 registration statement which was declared effective by the SEC on September 6, 2024. This registration statement includes (i) a base prospectus that covers the offering, issuance and sale by us of up to $300,000,000 of our common stock, preferred stock, debt securities, warrants and/or units and (ii) a sale agreement prospectus supplement that covers the offer and sale, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $55 million pursuant to our Open Market Sale Agreement℠ with Jefferies LLC.

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 trials.

Cash Flows

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

	Year ended December 31,	
	2024	2023
	(000's)	
Cash used in operating activities	$ (44,855)	$ (40,618)
Cash provided by investing activities	46,772	26,965
Cash provided by financing activities	17,338	2,935
Net increase (decrease) in cash and cash equivalents	$ 19,255	$ (10,718)

Operating Activities

During the year ended December 31, 2024, we used $44.9 million of cash in operating activities, resulting from our net loss of $49.4 million and the change in operating assets and liabilities of $4.1 million, offset by non-cash charges of $8.7 million. Our non-cash charges primarily consisted of stock-based compensation expense of $8.6 million.

During the year ended December 31, 2023, we used $40.6 million of cash in operating activities, resulting from our net loss of $42.5 million and the change in operating assets and liabilities of $2.9 million, offset by non-cash charges of $4.8 million. Our non-cash charges primarily consisted of stock-based compensation expense of $6.1 million.

Investing Activities

During the year ended December 31, 2024, cash provided by investing activities was $46.8 million, which was primarily attributed to the net proceeds from the sale of marketable securities of $46.8 million. During the year ended December 31, 2023 cash provided by investing activities was $27.0 million, which was primarily attributed to the net proceeds from the sale of marketable securities of $27.0 million.

Financing Activities

During the year ended December 31, 2024, cash provided by financing activities was $17.3 million. This was primarily from the issuance of stock pursuant to our ATM program for net proceeds of $17.6 million. During the year ended December 31, 2023, cash provided by financing activities was $2.9 million. This was primarily from the issuance of stock pursuant to our ATM program for net proceeds of $3.0 million.

Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates into their next clinical trial phases. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of clinical trials for our current product candidates or any future product candidates we may develop;
- the initiation, progress, timing, costs and results of nonclinical studies for our product candidates or any future product candidates we may develop;
- our ability to maintain our relationships with key collaborators;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or change their requirements on studies or trials 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, cash equivalents and marketable securities as of December 31, 2024 will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2027. 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 our product candidates, 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 our any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize our product candidates.

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

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2024 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by Period (000's)(3)				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Operating lease commitments(1)	$ 8,218	$ 733	$ 3,871	$ 2,977	$ 637
Manufacturing commitments(2)	2,550	2,550	—	—	—
Total	$ 10,768	$ 3,283	$ 3,871	$ 2,977	$ 637

(1) Reflects payments due for our leases of office and laboratory space in Boston, Massachusetts under an operating lease agreement that expires in May 2031.
(2) Amounts in the table reflect the non-cancelable purchase commitments under agreements with external CDMOs which we have engaged to manufacture clinical trial materials.
(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 which are cancelable.

Critical Accounting Estimates

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

While our significant accounting policies are described in more detail in Note 3 to our consolidated financial statements appearing in this Form 10-K, 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.

Stock Awards and Unit-Based Compensation

The following table summarizes stock awards and unit-based compensation expense:

	Year Ended December 31,	
	2024	2023
	(000's)	
Research and development	$ 2,971	$ 1,998
General and administrative	5,589	4,122
Total	$ 8,560	$ 6,120

See Notes 3 and 9 to our consolidated financial statements appearing in this Form 10-K for additional stock compensation information.

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 appearing in this Annual Report.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") was enacted. 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 common stock pursuant to an effective registration statement; (ii) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1.235 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.

Item 7A. 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 ("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 and marketable securities including corporate bonds, commercial paper certificates of deposit, U.S. government treasuries and asset backed securities, all of which are subject to interest rate risk. We limit our credit risk by investing in highly-rated securities. Changes in the general level of interest rates can affect the fair value of our investment portfolio. If interest rates in the general economy were to change, our holdings could change as a result.

Item 8. Financial Statements and Supplementary Data.

COMPASS THERAPEUTICS, INC. AND SUBSIDIARIES
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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Compass Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Compass Therapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024 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 these 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 entity'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.
Melville, New York
February 27, 2025

Compass Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets
(In thousands, except par value per share data)

	December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 43,483	$ 24,228
Marketable securities	83,239	128,233
Prepaid expenses and other current assets	6,029	1,420
Total current assets	132,751	153,881
Property and equipment, net	353	898
Operating lease, right-of-use ("ROU") asset	6,731	1,776
Other assets	568	320
Total assets	$ 140,403	$ 156,875
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,249	$ 4,090
Accrued expenses	6,287	2,514
Operating lease obligations, current portion	338	1,197
Total current liabilities	8,874	7,801
Operating lease obligations, net of current portion	6,296	536
Total liabilities	15,170	8,337
Commitments and Contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.0001 par value: 300,000 shares authorized; 137,820 shares issued and outstanding at December 31, 2024; 127,668 shares issued and outstanding at December 31, 2023	14	13
Additional paid-in-capital	489,692	463,796
Accumulated other comprehensive income	210	37
Accumulated deficit	(364,683)	(315,308)
Total stockholders' equity	125,233	148,538
Total liabilities and stockholders' equity	$ 140,403	$ 156,875

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

Compass Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share data)

	Year Ended December 31,	
	2024	**2023**
Licensing revenue	$ 850	$ —
Operating expenses:		
Research and development	42,342	38,120
General and administrative	15,133	12,243
Total operating expenses	57,475	50,363
Loss from operations	(56,625)	(50,363)
Other income	7,250	7,869
Net loss	$ (49,375)	$ (42,494)
Net loss per share - basic and diluted	$ (0.36)	$ (0.33)
Basic and diluted weighted average shares outstanding	137,384	127,027
Other comprehensive loss:		
Net loss	$ (49,375)	$ (42,494)
Unrealized gain on marketable securities	173	339
Comprehensive loss	$ (49,202)	$ (42,155)

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

Compass Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Changes in Stockholders' Equity
(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	126,302	$ 13	$ 454,741	$ (302)	$ (272,814)	$ 181,638
Common shares issued in ATM Offering, net	952	—	3,032	—	—	3,032
Common stock issued upon exercise of options	29	—	62	—	—	62
Share-based awards, net of tax remittance	385	—	(159)	—	—	(159)
Stock-based compensation	—	—	6,120	—	—	6,120
Unrealized gain on marketable securities	—	—	—	339	—	339
Net loss	—	—	—	—	(42,494)	(42,494)
Balance at December 31, 2023	127,668	$ 13	$ 463,796	$ 37	$ (315,308)	$ 148,538
Common shares issued, net of $0.5 million costs	9,790	$ 1	$ 17,568	$ —	$ —	$ 17,569
Share-based awards, net of tax remittance	362	—	(232)	—	—	(232)
Stock-based compensation	—	—	8,560	—	—	8,560
Unrealized gain on marketable securities	—	—	—	173	—	173
Net loss	—	—	—	—	(49,375)	(49,375)
Balance at December 31, 2024	137,820	$ 14	$ 489,692	$ 210	$ (364,683)	$ 125,233

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

Compass Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (49,375)	$ (42,494)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	589	699
Share-based compensation	8,560	6,120
Amortization of premium and discount on marketable securities	(1,651)	(3,226)
ROU asset amortization	1,164	1,191
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4,857)	6,762
Accounts payable	(1,841)	708
Accrued expenses	3,773	(9,176)
Operating lease liability	(1,217)	(1,202)
Net cash used in operating activities	(44,855)	(40,618)
Cash flows from investing activities:		
Purchases of marketable securities	(88,158)	(155,418)
Proceeds from sale or maturities of marketable securities	134,974	182,413
Purchases of property and equipment	(44)	(30)
Net cash provided by in investing activities	46,772	26,965
Cash flows from financing activities:		
Proceeds from issuance of common stock	18,113	3,126
Issuance costs from issuance of common stock	(543)	(94)
Proceeds from exercise of stock options	—	62
Taxes related to the vesting of RSUs	(232)	(159)
Net cash provided by financing activities	17,338	2,935
Net change in cash and cash equivalents	19,255	(10,718)
Cash and cash equivalents at beginning of year	24,228	34,946
Cash and cash equivalents at end of year	$ 43,483	$ 24,228
Supplemental disclosure of cash flow information		
Unrealized gain on marketable securities	$ (173)	$ (339)

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

1. Formation and Business of the Company

Compass Therapeutics, Inc. ("Compass" or the "Company") is a clinical-stage, oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics to treat multiple human diseases. Our scientific focus is on the relationship between angiogenesis and the immune system. Our pipeline includes novel product candidates that leverage our understanding of the tumor microenvironment, including both angiogenesis-targeted agents and immune-oncology focused agents. These product candidates are designed to optimize critical components required for an effective anti-tumor response to cancer. These include modulation of the microvasculature via angiogenesis-targeted agents; induction of a potent immune response via activators on effector cells in the tumor microenvironment; and alleviation of immunosuppressive mechanisms used by tumors to evade immune surveillance. We plan to advance our product candidates through clinical development as both standalone therapies and in combination with our proprietary drug candidates as long as their continued development is supported by clinical and nonclinical data. References to Compass or the Company herein include Compass Therapeutics, Inc. and its wholly-owned subsidiaries.

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

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 consolidated financial statements are issued.

Since its inception, the Company has funded its operations primarily with proceeds from the sale of its equity securities. The Company has incurred recurring losses since its inception and had an accumulated deficit of $365 million on December 31, 2024. The Company expects to continue to generate operating losses for the foreseeable future. The Company expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements into the first quarter of 2027. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

The Company is subject to risks common to early stage companies in the biotechnology industry including, but not limited to: having a limited operating history and no products approved for commercial sale; having a history of significant losses; its need to obtain additional financing; dependence on its ability to advance its current and future product candidates through clinical trials, marketing approval and commercialization; the lengthy and expensive nature and uncertain outcomes of the clinical development process; the lengthy, time consuming and unpredictable nature of the regulatory approval process; the results of preclinical studies and early stage clinical trials that may not be predictive of future results; dependence on its key personnel; risks related to patent protection and the Company's pending patent applications; dependence on third party collaborators for the discovery, development and commercialization of current and future product candidates; and significant competition from other biotechnology and pharmaceutical companies. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

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 Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Compass Therapeutics, Inc., and its wholly-owned subsidiaries, including Compass Therapeutics LLC, Compass Therapeutics Advisors Inc., Trigr Therapeutics, Inc. and Compass Therapeutics Securities Corporation. 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, useful lives of equipment, interest rate and term operating lease ROU and liability, the percentage of completion of contractual arrangements, future cash expenditures for liquidity estimates, 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 prospectively 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 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 or commercial paper. Cash equivalents are stated at cost, which approximates market value. Cash and cash equivalents were $43.5 million and $24.2 million on December 31, 2024 and 2023, respectively.

Marketable Securities

All of the Company's investment securities are debt securities and bank instruments. The Company carries these investments at fair value. Unrealized gains and losses, if any, are reported as a separate component of stockholders' equity. The cost of investment securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. Realized gains and losses, if any, are also included in interest income. The cost of securities sold is based on the specific identification method.

Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash equivalents and marketable securities. The Company invests its excess cash primarily in money market funds, U.S. treasury notes, and high quality, marketable debt instruments of corporations in accordance with the Company's investment policy. The Company's investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of its investments to preserve principal and maintain liquidity. The Company has not experienced any realized losses related to its cash equivalents and marketable securities.

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 consolidated balance sheet and any resulting gains or losses are included in the consolidated statement of operations and comprehensive loss 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.

Impairment of Long-Lived Assets

Long-lived assets consist of property, equipment and right-of-use ("ROU") assets. 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 the 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 years ended December 31, 2024 and 2023.

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.

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 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 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 to determine 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.

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.

Stock-Based Compensation

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 service 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.

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.

Stock price: The stock price used to value equity awards is based on the closing price of the Company's common stock as reported on the date of the grant. For equity awards issued after June 2020 until the Company started trading on a public market in the second quarter of 2021, the valuation of the Company's common stock was $5.00 per share, which was the share price paid by outside investors in the Company's Private Placement in June 2020.

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 – The expected volatility is calculated based on the historical volatility of our common stock over the expected term of the option.

Risk-free interest rate – The risk-free rate assumption is based on 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.

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 exercise or conversion of securities, such as convertible preferred stock, stock options, restricted stock units, unvested restricted stock awards 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 December 31, 2024 and 2023 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	December 31,	
	2024	2023
	(000's)	
Restricted stock units	3,766	1,500
Stock options	14,062	7,876
Total	17,828	9,376

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all of the deferred tax benefits will not be realized.

The Company files income tax returns in the U.S. Federal jurisdiction and in various states. The Company has tax net operating loss carryforwards that are subject to examination for a number of years beyond the year in which they were generated for tax purposes. Since a portion of these net operating loss carryforwards may be utilized in the future, many of these net operating loss carryforwards will remain subject to examination.

New Accounting Pronouncements

In December 2023, the FASB issued Accounting Standards Update ("ASU") No. 2024-09, *Income Taxes (Topic 740)*: *Improvements to Tax Disclosures*. The purpose of ASU 2024-09 is to enhance the transparency and decision usefulness of income tax disclosures. The ASU requires a significant expansion of the granularity of the income tax rate reconciliation as well as an expansion of other income tax disclosures. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. This will result in additional disclosures being included in our consolidated financial statements, once adopted. The Company is evaluating the impact of ASU 2024-09 and does not expect ASU-2024-09 to have a significant impact on the consolidated financial statements.

Recently Adopted Accounting Pronouncements

The Company adopted ASU No. 2023-07, *Segment Reporting—Improvements to Reportable Segment Disclosures* (Topic 280) as of January 1, 2024. The amendments in ASU 2023-07 improve financial reporting by requiring disclosure of incremental segment information on an annual and interim basis for all public entities to enable investors to develop more decision-useful financial analyses. ASU 2023-07 requires a public entity to report a measure of segment profit or loss that the chief operating decision maker (CODM) uses to assess segment performance and make decisions about allocating resources. ASU 2023-07 also requires other specified segment items and amounts, such as depreciation, amortization, and depletion expense, to be disclosed under certain circumstances. The amendments in ASU 2023-07 do not change or remove those disclosure requirements. The amendments in ASU 2023-07 also do not change how a public entity identifies its operating segments, aggregates those operating segments, or applies the quantitative thresholds to determine its reportable segments. The amendments in ASU 2023-07 are effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024, adopted retrospectively. The adoption of ASU 2023-07 did not have a material effect on the Company's consolidated financial statements or disclosures.

There are no other pending accounting pronouncements that are expected 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:

	Fair Value Measurements as of December 31, 2024 (000's):			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
Assets				
Corporate bonds	$ —	$ 44,963	$ —	$ 44,963
Certificates of deposit	—	15,269	—	15,269
Commercial paper	12,084	—	—	12,084
U.S. government treasuries	4,399	—	—	4,399
Asset-backed securities	—	6,524	—	6,524
Money market funds (cash equivalents)	23,880	—	—	23,880
Total assets	$ 40,363	$ 66,756	$ —	$ 107,119

	Fair Value Measurements as of December 31, 2023 (000's):			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
Assets				
Corporate bonds	$ —	$ 54,281	$ —	$ 54,281
Certificates of deposit	—	18,866	—	18,866
Commercial paper	28,534	—	—	28,534
U.S. government treasuries	16,080	—		16,080
Asset-backed securities	—	10,472	—	10,472
Money market funds (cash equivalents)	575	—	—	575
Total assets	$ 45,189	$ 83,619	$ —	$ 128,808

5. Marketable Securities

The objectives of the Company's investment policy are to ensure the safety and preservation of invested funds, as well as to maintain liquidity sufficient to meet cash flow requirements. The Company invests its excess cash in securities issued by financial institutions, commercial companies, and government agencies that management believes to be of high credit quality in order to limit the amount of its credit exposure. The Company has not realized any net losses from its investments.

Unrealized gains and losses on investments that are available for sale are recognized in accumulated comprehensive loss, unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company periodically reviews its investments for other than temporary declines in fair value below cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

The Company believes the individual unrealized losses represent temporary declines primarily resulting from interest rate changes. Realized gains and losses are included in other income in the consolidated statements of operations and comprehensive loss and are determined using the specific identification method with transactions recorded on a trade date basis. The Company classifies marketable securities that are available for use in current operations as current assets on the consolidated balance sheet.

The following tables summarize marketable securities held at December 31, 2024 and 2023 (in thousands):

	Fair Value Measurements as of December 31, 2024 Using:			
	Amortized Cost	Unrealized gains	Unrealized Losses	Fair Value
Assets				
Corporate bonds	$ 44,794	$ 175	$ (6)	$ 44,963
Certificates of deposit	15,262	8	(1)	15,269
Commercial paper	12,081	5	(2)	12,084
Asset-backed securities	6,484	40	—	6,524
U.S. government treasuries	4,408	2	(11)	4,399
Total assets	$ 83,029	$ 230	$ (20)	$ 83,239

	Fair Value Measurements as of December 31, 2023 Using:			
	Amortized Cost	Unrealized gains	Unrealized Losses	Fair Value
Assets				
Corporate bonds	$ 54,256	$ 74	$ (49)	$ 54,281
Certificates of deposit	18,850	17	(1)	18,866
Commercial paper	28,507	30	(3)	28,534
Asset-backed securities	10,456	23	(7)	10,472
U.S. government treasuries	16,127	3	(50)	16,080
Total assets	$ 128,196	$ 147	$ (110)	$ 128,233

	As of December 31,	
	2024	2023
Maturing in one year or less	56,386	93,117
Maturing after one year through two years	26,853	35,116
Total	$ 83,239	$ 128,233

6. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2024	2023
	(000's)	
Equipment	$ 4,716	$ 5,167
Furniture and fixtures	22	22
Leasehold improvements	1,612	1,612
Software	364	364
Total property and equipment–at cost	6,714	7,165
Less: Accumulated depreciation and amortization	(6,361)	(6,267)
Property and equipment, net	$ 353	$ 898

Total depreciation and amortization expense for years ended December 31, 2024 and 2023, was $0.6 million and $0.7 million, respectively.

7. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2024	2023
	(000's)	
Project expenses	$ 2,873	$ 336
Compensation and benefits	2,793	1,938
Other	621	240
Total accrued expenses	$ 6,287	$ 2,514

Project expenses in 2024 were primarily made up of $2.6 million of accrued manufacturing expenses related to minimum contractual obligations. Compensation and benefits primarily increased from 2023 based on accrued payroll related to the departure of the CEO of $0.7 million.

8. Stockholders' Equity

In the first quarter of 2024, the Company sold through its at-the-market ("ATM") agreement with Jefferies LLC, 9,790,577 shares of common stock at an average price of $1.85 for total proceeds of $18.1 million and net proceeds of $17.6 million.

In the second quarter of 2023, the Company sold through its ATM agreement with Jefferies LLC, 951,873 shares of common stock at an average price of $3.28 for total proceeds of $3.1 million and net proceeds of $3.0 million.

9. Stock-Based Compensation

Stock-based compensation expense for the years ended December 31, 2024 and 2023 was classified in the consolidated statements of operations as follows:

	Year Ended December 31,	
	2024	2023
	(000's)	
Research and development	$ 2,971	$ 1,998
General and administrative	5,589	4,122
Total	$ 8,560	$ 6,120

2020 Plan

In June 2020, the Company's board of directors adopted the 2020 Plan and reserved 2.9 million shares of common stock for issuance under this plan. 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 4% of the outstanding number of shares of our common stock on the immediately preceding December 31 or such number of shares as determined by the plan administrator no later than the immediately preceding December 31. As of December 31, 2024, 1.4 million shares remain available for future grant. On January 1, 2025, an additional 5.5 million shares became available for issuance based on 4% of the outstanding shares of common stock, for a total of 6.9 million shares available for issuance.

The 2020 Plan authorizes the board of directors or a committee of the board to grant incentive stock options, nonqualified stock options, restricted stock awards and restricted stock units ("RSUs") 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.

Stock Options:

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

	Number of Nonvested Options (000's)	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (000's)
Outstanding at December 31, 2022	5,378	$ 3.89	8.24	$ 6,316
Granted	2,803	$ 3.69	9.18	$ —
Exercised	(29)	$ 1.75	—	$ 35
Forfeited/cancelled	(276)	$ 4.29	—	$ 164
Outstanding at December 31, 2023	7,876	$ 3.81	8.05	$ 11
Granted	6,193	$ 1.58	7.10	$ —
Exercised	—	$ —	—	$ —
Forfeited/cancelled	(7)	$ 3.04	—	$ —
Outstanding at December 31, 2024	14,062	$ 2.83	6.23	$ 579
Vested at December 31, 2024	6,551	$ 3.67	5.28	$ 49

For the year ended December 31, 2024, the weighted average grant date fair value for options granted was $1.13. The aggregate intrinsic value for options vested and outstanding as of December 31, 2024 and 2023 was $579 thousand and $11 thousand, respectively. As of December 31, 2024, the unrecognized compensation cost related to outstanding options was $11.1 million, expected to be recognized over a weighted average period of approximately 1.5 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 years ended December 31, 2024 and 2023 were as follows:

	Year Ended December 31,	
	2024	2023
Expected term (in years)	6.0	6.0
Risk-free rate	3.92%	3.83%
Expected volatility	81%	87%

RSUs:

The following table summarizes the RSU activity for the 2020 Plan:

	Shares (000's)	Weighted Average Price Per Share	Weighted Average Fair Value (000's)
Unvested, December 31, 2022	900	$ 3.83	$ 3,447
Granted	900	3.93	3,537
Vested	(300)	3.83	(1,149)
Forfeited or canceled	—	—	—
Unvested, December 31, 2023	1,500	$ 3.83	$ 5,745
Granted	2,791	$ 1.89	$ 5,275
Vested	(525)	3.87	(2,032)
Forfeited or canceled	—	—	—
Unvested, December 31, 2024	3,766	$ 2.41	$ 9,076

Weighted average price per share is the weighted grant price based on the closing market price of each of the stock grants. The weighted average fair value is the weighted average share price times the number of shares.

As of December 31, 2024, remaining unrecognized compensation cost related to RSUs to be recognized in future periods totaled $7.0 million, which is expected to be recognized over a weighted average period of 1.5 years. As of December 31, 2024, the total unrecognized compensation cost from all plans to be recognized in future periods totaled approximately $18.1 million.

10. License, Research and Collaboration Agreements

Collaboration Agreements

ABL Bio Corporation ("ABL Bio") Agreements

In November 2018, the Company and ABL Bio, a South Korean biotechnology company, entered into an exclusive global (excluding South Korea) license agreement which granted the Company a license to tovecimig (ABL001), ABL Bio's bispecific antibody targeting DLL4 and VEGF-A. Under the terms of the agreement, the two companies would jointly develop tovecimig, with ABL Bio responsible for development of tovecimig throughout the end of Phase 1 clinical trials and the Company responsible for the development of tovecimig from Phase 2 and onward. ABL Bio received a $5 million upfront payment and $6 million development milestone payment. In addition, ABL Bio is eligible to receive up to $96 million of development and regulatory milestone payments, and up to $303 million of commercial milestone payments and tiered single-digit royalties on net sales of tovecimig in oncology. ABL Bio is also eligible to receive up to $75 million in development and regulatory milestones and up to $110 million in commercial milestone payments and tiered, single-digit royalties on net sales of tovecimig in ophthalmology.

In May 2021, TRIGR and ABL Bio terminated license agreements to several preclinical assets. As a result of the return of these assets to ABL Bio and termination of the license agreements, the Company is eligible to receive royalty payments if ABL Bio develops or licenses two bispecific antibodies that were previously licensed to TRIGR.

Adimab Agreement

The Company entered into a collaboration agreement with Adimab, LLC on October 16, 2014. The agreement 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 for certain antibodies, including our product candidate, CTX-471. There were no milestone payments made during 2024. As of December 31, 2024, future potential milestone payments in connection with this agreement amounted to $2.0 million.

11. Commitments and Contingencies

Leases

The Company accounts for operating leases on a straight-line basis over the lease term, with recognition of a right-of-use asset and a corresponding lease liability, initially measured at the present value of the lease payments. For leases with a term of 12 months or less, we recognize lease expense on a straight-line basis over the lease term.
The Company has evaluated its leases under ASC 842, *Leases*, and determined that it has one lease that is classified as an operating lease. The classification of this lease is consistent with the Company's determination under the previous accounting standard.

When available, the Company will use the rate implicit in the lease to discount lease payments to present value; however, the Company's current lease does not provide an implicit rate. Therefore, the Company used its incremental borrowing rate of 6.25% to discount the lease payments based on the date of the lease commencement.

The Company has one operating lease for its corporate office and laboratory facility ("Facility") that was signed in December 2020. The Company moved into the Facility in January 2021. The Facility lease has an initial term of four years and five months, beginning on January 1, 2021.

The terms of the Facility lease were modified effective September 27, 2024 through the execution of a new lease. The modified terms extended the non-cancelable lease term through May 2031. The modified terms also included the right to use an additional 10,724 square feet that is expected to commence and be available for the Company's use in May 2025. The classification and incremental borrowing rate for the lease did not change as a result of this lease modification. Right-of-use assets obtained in exchange for new operating lease liabilities due to the lease modification were $6.1 million for a total right-of-use assets as of December 31, 2024 of $6.7 million. The remaining lease term of the Facility lease is 6.4 years as of December 31, 2024. The Company has $568 thousand of restricted cash associated with an irrevocable letter of credit required by the landlord to enter into this lease.

Lease costs related to the Facility were $1.1 million and $1.3 million for the years ending December 31, 2024 and 2023, respectively. Cash paid for this lease was $1.4 million and $1.3 million for the years ended December 31, 2024 and 2023, respectively.
The table below presents the undiscounted cash flows for the lease term. The undiscounted cash flows are reconciled to the operating lease liabilities recorded on the consolidated balance sheets:

	(000's)
Years ending December 31,	
2025	$ 733
2026	1,018
2027	1,412
2028	1,441
Thereafter	3,614
Total minimum lease payments	8,218
Less: amount of lease payments representing interest	(1,584)
Present value of future minimum lease payments	6,634
Less: operating lease obligations, current portion	(338)
Operating lease obligations, long-term portion	$ 6,296

Defined Contribution Plan

The Company has a 401(k) defined contribution plan (the "401(k) Plan") for substantially all its employees. Eligible employees may make pre-tax or post-tax (Roth) contributions to the 401(k) Plan up to statutory limits. Since January 1, 2020, the Company has been matching employee contributions to the plan up to 4% of salary. On July 1, 2023, the Company increased the employee matching contribution from 4% to 6%. The Company made matching contributions of $0.3 million and $0.2 million for the years ended December 31, 2024 and 2023, respectively.

12. Other income

Other income consisted of interest income from investments on marketable securities of $7.3 million and $7.9 million for the years ended December 31, 2024 and 2023, respectively.

13. Income Taxes

The Company had no income tax for the years ended December 31, 2024 and 2023.
The effective tax rate of our provision for income taxes differs from the federal statutory rate for the periods presented as follows:

	December 31,	
	2024	**2023**
Statutory rate	21.0%	21.0%
State taxes	7.0%	7.9%
Share-based compensation & other nondeductible expenses	-1.1%	1.5%
Research credits	5.8%	7.3%
Other	-0.7%	-0.6%
Change in valuation allowance	-32.0%	-37.1%
Total	0.0%	0.0%

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. In determining the need for a valuation allowance, management reviews both positive and negative evidence, including current and historical results of operations, future income projections and the overall prospects of our business. Based upon management's assessment of all available evidence, the Company believes that it is more-likely-than-not that the deferred tax assets will not be realizable, and therefore, a valuation allowance has been established. The valuation allowance for deferred tax assets was approximately $59.5 million and $43.8 million as of December 31, 2024 and 2023, respectively.

As of December 31, 2024, the Company has U.S. federal and state net operating loss carryforwards ("NOLs") of $79.8. million and $80.0 million, respectively. As of December 31, 2024, the Company has federal and state research and development credit carryforwards ("R&D credits") of $7.3 million and $2.4 million, respectively. For income tax purposes, federal NOLs will not expire since they were generated after 2017 and federal R&D credits will begin expiring in 2039. For income tax purposes, state NOLs and state R&D credits will begin to expire in 2040 and 2031, respectively.

Net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service (the "IRS") and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50% as defined under Sections 382 and 383 in the Internal Revenue Code, which could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the Company's value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not yet conducted a study to determine if any such limitation exists.

The Tax Cuts and Jobs Act of 2017 ("TCJA") amended IRC Section 174 to require capitalization of all research and developmental (R&D) costs incurred in tax years beginning after December 31, 2021. These costs are required to be amortized with a half-year convention over five years if the R&D activities are performed in the U.S., or over 15 years if the activities were performed outside the U.S. The Company capitalized approximately $39.9 million and amortized $14.3 million of R&D expenses incurred for the year ended December 31, 2024.

As of December 31, 2024 and 2023, the Company had no uncertain tax positions, and as such, no related interest or penalties have been recorded in the statements of operations and comprehensive loss. The Company recognizes interest and penalties related to uncertain tax positions as a component of income tax expense. All tax years of the Company from inception are open to examination by federal tax and state tax authorities. To the extent utilized in future years' tax returns, net operating loss carryforwards at December 31, 2024 will remain subject to examination until the respective tax year is closed. The Company has not been informed by any tax authorities for any jurisdiction that any of its tax years is under examination as of December 31, 2024.

Significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31,	
	2024	2023
Deferred tax assets	(000's)	
Federal net operating loss carryforwards	$ 16,775	$ 13,760
State net operating loss carryforwards	5,063	3,719
Research and development credits	9,252	6,387
Section 174 Capitalization	22,724	15,525
Share-based compensation	3,922	2,701
Lease liabilities	1,812	474
Capitalized licensing fees	1,375	1,484
Other	494	234
Subtotal	61,417	44,284
Less valuation allowance	(59,521)	(43,799)
Deferred tax assets, net of valuation allowance	1,896	485
Deferred tax liabilities		
Right-of-use assets	(1,839)	(485)
Other	(57)	—
Net deferred tax assets	$ —	$ —

14. Segment Information

Segment reporting is prepared on the same basis that our chief executive officer, who is our CODM, manages the business, makes operating decisions and assesses performance. The Company operates in one segment. The Company's business is research and development of drug candidates. Costs, including supplies, outsourced development, personnel costs and other research and development costs are tracked to reported by major program. Facility and equipment costs are not allocated to programs. Research and development expenses are summarized by program in the table below:

	Year Ended December 31,	
	2024	2023
	(000's)	
Licensing revenue	$ 850	$ —
Personnel	9,918	7,568
General	3,965	3,647
Tovecimig	23,177	21,824
CTX-471	2,879	2,846
CTX-8371	2,403	2,235
Research and development	42,342	38,120
Personnel	3,818	2,623
General	4,661	4,054
Stock-based compensation	6,654	5,566
General and administrative	15,133	12,243
Other income	7,250	7,869
Net loss	$ (49,375)	$ (42,494)

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

Under the supervision of and with the participation of our management, including our principal executive officer, our principal financial officer and our principal accounting officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2024, the end of the period covered by this Form 10-K. The term "disclosure controls and procedures," as set forth in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Based on this evaluation, management concluded that our disclosure controls and procedures were effective as of December 31, 2024.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) 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. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our consolidated financial statements; providing reasonable assurance that receipts and expenditures of company assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of company assets that could have a material effect on our consolidated financial statements would be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our consolidated financial statements would be prevented or detected.

We are 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 this Form 10-K. This assessment includes 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. Management conducted an evaluation of the effectiveness, as of December 31, 2024, of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013). Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2024.

As an "emerging growth company" under the JOBS Act, we are exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. As a result, our independent registered public accounting firm has not audited or issued an attestation report with respect to the effectiveness of our internal control over financial reporting as of December 31, 2024.

Changes in Internal Control over Financial Reporting

During the quarter ended December 31, 2024, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Rule 10b5-1 Trading Plans

During the three months December 31, 2024, none of our directors or officers adopted, materially modified, or terminated any contract, instruction, or written plan for the purchase or sale our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any non-Rule 10b5-1 trading arrangement.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except to the extent provided below, the information required by this Item 10 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission ("SEC"), with respect to our 2025 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2025 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2025 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2025 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2025 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(1) See Index to the Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

(2) All financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the accompanying notes.

(3) Exhibits

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 June 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)
3.4	Agreement and Plan of Merger and Reorganization by and among Compass Therapeutics, Inc. Compass Intermediate Acquisition Company, Inc., Compass Acquisition Company, LLC, Trigr Therapeutics, Inc. and Peng Ventures, LLC, as Stockholder Representative (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed with the SEC on May 13, 2021)
4.1	Specimen Certificate for Common Stock (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 filed with the SEC on October 19, 2020)
4.2	Description of Registered Securities (incorporated by reference to Exhibit 4.2 to the Annual Report on Form 10-K filed with the SEC on March 5, 2021)
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#	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)
10.4#	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)

10.5#	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)
10.6	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)
10.7	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)
10.8†	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)
10.9	Sublease Agreement, effective as of December 1, 2020, by and between Roche Diagnostic Operations, Inc. and Compass Therapeutics, Inc. (incorporated by reference to Exhibit 10.16 to the Annual Report on Form 10-K filed with the SEC on March 5, 2021)
10.10	Lease Agreement, effective as of September 27, 2024, by and between ICE BOX, LLC and Compass Therapeutics, Inc. (incorporated by reference to Exhibit 10.13 to the Quarterly Report on Form 10-Q filed with the SEC on November 12, 2024)
10.11*#	Employment Agreement between Compass Therapeutics, Inc. and Thomas J. Schuetz, M.D., Ph.D., dated January 8, 2024 (incorporated by reference to Exhibit 10.10 to the Annual Report on Form 10-K filed with the SEC on March 21, 2024)
10.12*#	Employment Agreement between Compass Therapeutics, Inc. and Barry Shin, dated December 9, 2024 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on December 10, 2024)
10.13	Separation Agreement, dated May 28, 2024, by and between Compass Therapeutics, Inc. and Vered Bisker-Leib, PhD (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on May 28, 2024)
10.14	Consulting Agreement, dated May 28, 2024, by and between Compass Therapeutics, Inc. and Vered Bisker-Leib, PhD (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on May 28, 2024)
10.15	Research and Development Collaboration and License Agreement, dated November 30, 2018, between Trigr Therapeutics, Inc. and ABL Bio Inc. (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed with the SEC on August 16, 2021)
19.1	Insider Trading Compliance Policy
21.1	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)
23.1*	Consent of CohnReznick LLP, independent registered public accounting firm
24.1*	Power of Attorney (included on signature page)

31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	Registrant's Compensation Clawback Policy (incorporated by reference to Exhibit 97.1 to the Annual Report on Form 10-K filed with the SEC on March 21, 2024)
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

# Indicates a management contract or any compensatory plan, contract or arrangement.
* Filed herewith.
** The certification furnished in Exhibit 32.1 hereto is deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.
† Portions of this exhibit have been omitted in accordance with the rules of the SEC.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Compass Therapeutics, Inc.

Date: February 27, 2025

By: /s/ Thomas Schuetz

Thomas Schuetz
Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

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

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

Name	Title	Date
/s/ Thomas J. Schuetz **Thomas J. Schuetz**	Chief Executive Officer and Vice Chair of the Board (Principal Executive Officer)	February 27, 2025
/s/ Barry Shin **Barry Shin**	Chief Financial Officer (Principal Financial Officer)	February 27, 2025
/s/ Neil Lerner **Neil Lerner**	Chief Accounting Officer (Principal Accounting Officer)	February 27, 2025
/s/ Carl L. Gordon **Carl L. Gordon**	Chair of the Board	February 27, 2025
/s/ Phil Ferneau **Phil Ferneau**	Director	February 27, 2025
/s/ Mary Ann Gray **Mary Ann Gray**	Director	February 27, 2025
/s/ Ellen Chiniara **Ellen Chiniara**	Director	February 27, 2025
/s/ James Boylan **James Boylan**	Director	February 27, 2025
/s/ Richard Lindahl **Richard Lindahl**	Director	February 27, 2025