2023 Annual Report

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, 2023

☐ **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 001-39787

BIOATLA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**85-1922320**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11085 Torreyana Road, San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code:
(858) 558-0708

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	**BCAB**	**The Nasdaq Global 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 ☐ or No ☒

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

Indicate by check mark whether the registrant 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 Act). Yes ☐ No ☒

As of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $91.0 million based on the closing sales price of $3.00 per share as reported on the Nasdaq Global Market.

As of March 22, 2024, the number of shares of the registrant's common stock outstanding was 48,096,717 and the number of shares of the registrant's Class B common stock outstanding was 0.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant's definitive proxy statement (the "Proxy Statement") relating to its 2024 Annual Meeting of Stockholders. The Proxy Statement will be filed with the United States Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

BIOATLA, INC.
Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2023

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PART I

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to known and unknown risks, uncertainties and assumptions, including risks described in the section titled "Risk Factors" set forth in Part I, Item 1A of this Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission (the "SEC"). It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Annual Report on Form 10-K may not occur, and actual results may differ materially and adversely from those anticipated or implied in the forward-looking statements. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical trials;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates and other positive results;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our manufacturing, commercialization and marketing capabilities and strategy;
- our plans and strategies to develop and commercialize our CAB antibodies;
- our plans to further develop our technology platform and expand our pipeline of product candidates;
- the potential benefits and advantages of our current and future product candidates that we may develop from our patented technology platform;
- the timing or likelihood of regulatory filings and approvals for our product candidates;
- regulatory developments in the United States and Europe and other foreign countries;
- our expectations and plans to obtain funding for our operations, including from our existing and potential future collaboration and licensing agreements;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our technology platform and product candidates;
- the potential benefits of our strategic relationships and our plans to pursue additional strategic relationships;
- 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 estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- the impact of health epidemics and outbreaks, including the COVID-19 pandemic, on our business, financial condition, results of operations, and prospects.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report on Form 10-K.

You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we do not intend to update any of these forward-looking statements after the date of this Annual Report on Form 10-K or to conform these statements to actual results or revised expectations.

You should read this Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

This Annual Report on Form 10-K contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. We obtained the industry, market and similar data set forth in this report from our own internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. While we believe that the data we use from third parties are reliable, we have not separately verified these data. Further, while we believe our internal research is reliable, such research has not been verified by any third party. You are cautioned not to give undue weight to any such information, projections and estimates.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to "BioAtla," "we," "us" and "our" refer to BioAtla, Inc.

ITEM 1. Business

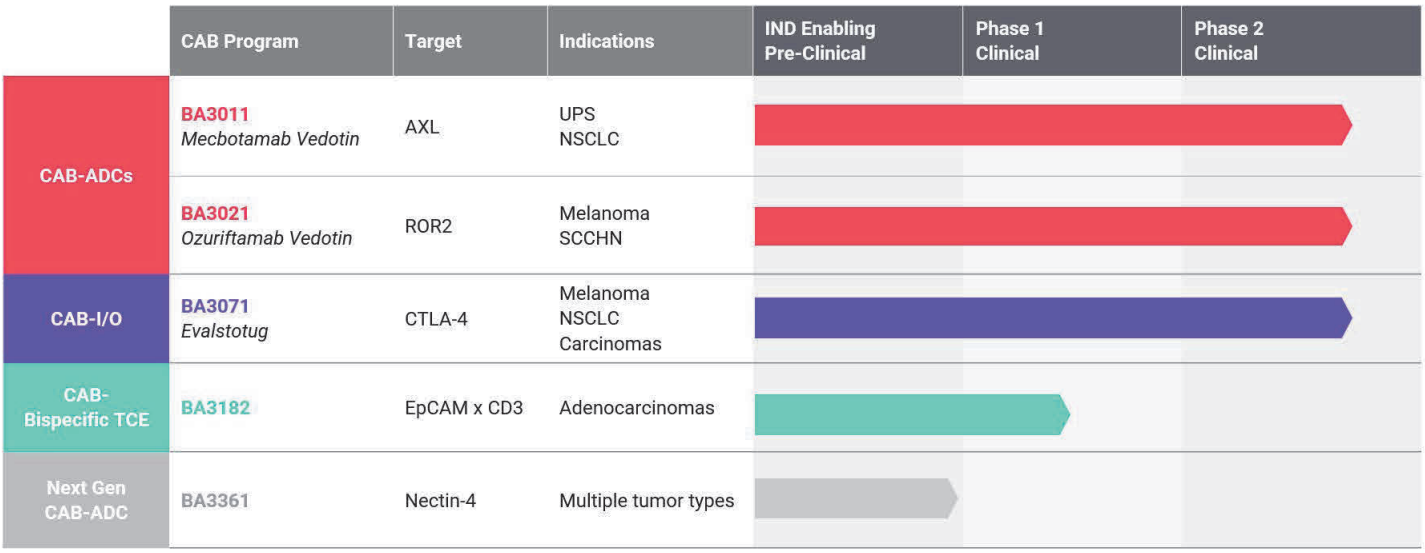
Overview

We are a clinical-stage biopharmaceutical company developing our novel class of highly specific and selective antibody-based therapeutics for the treatment of solid tumor cancer. Our conditionally active biologics ("CAB" or "CABs") capitalize on our proprietary discoveries with respect to tumor biology, enabling us to target known and widely validated tumor antigens that have previously been difficult or impossible to target. Our novel CAB therapeutic candidates exploit characteristic pH differences between the tumor microenvironment and healthy tissue. Unlike healthy tissue, the tumor microenvironment is acidic, and we have designed our antibodies to selectively bind to their targets on cancer cells under acidic pH conditions but not on targets in normal tissues. Our approach is to identify the necessary targeting and potency required for cancer cell destruction, while aiming to eliminate or greatly reduce on-target, off-tumor toxicity—one of the fundamental challenges of existing cancer therapies. The enhanced selectivity of our CAB technology has the potential to greatly improve the benefit-risk ratio for the patient and allows us to deliver desired drug levels either as monotherapy or utilizing unique multi-targeted or combination therapies that are currently difficult or impossible to develop. Additionally, the combination of reversible binding with the selective, precision capability of our CAB technology enables both increased antibody potency and reduced toxicity. By exploiting our novel understanding of tumor biology, we believe that our proprietary CAB technology has the potential to transform antibody-based cancer therapy.

Our goal is to develop well-tolerated, novel cancer therapies that provide cures or extended survival to ensure patients' improved quality of life. Studies have shown that, as a drug class, antibodies have transformed oncology treatment and include some of the best-selling therapies on the biopharmaceutical market. The broad applicability of our CAB technology allows us to develop a wide array of product candidate modalities, such as monoclonal antibodies, antibody-drug conjugates, or ADCs, T cell-engaging bispecific antibodies and chimeric antigen receptor T cells, or CAR-T cells. In 2021, we published a paper in the Proceedings of the National Academy of Sciences (PNAS) describing a novel mechanism using physiological chemicals as Protein-activated Chemical Switches™, or PaCS™, for generating CAB antibodies. Initially, we applied the reversible binding and precision capability of our CAB technology to advance next-generation ADC therapies. We have also developed antibodies for immuno-oncology and for bispecific, T cell engagement. The bispecific CAB antibodies are comprised of two different binding specificities, which allows the antibody to bind to two specific targets at the same time, generally one target on the tumor cell and one target on an immune system cell.

Our pipeline

We believe that there is significant potential to improve therapeutics for our patients with our proprietary CAB antibody technology across well-validated oncology targets in solid tumors. The following table summarizes our current product candidate pipeline.



Mecbotamab vedotin (BA3011): Our lead clinical stage product candidate, mecbotamab vedotin, or BA3011, is a CAB ADC that targets AXL, a protein kinase receptor that is expressed on the surface of many tumors. AXL is considered to be a driver of many cellular processes that are critical for the development, growth and spread of tumors, including proliferation, invasiveness and migration, stemness, which is related to core stem cell properties such as self-renewal and differentiation, angiogenesis, or the growth of blood vessels, and immune modulation. AXL has been shown to be involved in the epithelial-mesenchymal transition, or EMT, a process by which epithelial cells lose their cell polarity and cell-cell adhesion, and gain migratory and invasive properties to become mesenchymal stem cells, or MSCs. MSCs are home to developing aggressive tumors, where they exacerbate cancer cell proliferation, motility, invasion and metastasis, foster angiogenesis, promote tumor fibrosis and suppress antitumor immune responses. Multiple therapeutic agents that target AXL have been developed and investigated in clinical trials. A number of small-molecule AXL kinase inhibitors have been developed; however, the majority of these inhibitors, including one that is approved, are not highly selective for AXL. Although other non-CAB anti-AXL antibodies and ADCs have shown encouraging clinical signs of antitumor activity, adverse events, such as high-grade constipation and peripheral neuropathy, were particularly pronounced and led to discontinuation of clinical development of some candidates.

Mecbotamab vedotin is an ADC consisting of a CAB humanized immunoglobulin G, or IgG1, anti-AXL monoclonal antibody. The core antibody is conjugated using a cleavable linker attached to the well-known and proven toxin monomethyl auristatin E, or MMAE. Mecbotamab vedotin is designed to specifically and reversibly bind to AXL in conditions found within the tumor microenvironment, thus conferring a selectivity binding advantage for tumors over normal cells. Upon binding of mecbotamab vedotin to AXL on the surface of tumor cells, it is internalized and the MMAE cytotoxin is released, thus killing the cancer cell.

We are developing mecbotamab vedotin as a potential therapeutic for multiple solid tumor types, including soft tissue and bone sarcoma and non-small cell lung cancer (NSCLC), with other potential indications in the future. The Office of Orphan Products Development (OOPD) at the FDA has granted Orphan Drug Designation to mecbotamab vedotin for the treatment of soft tissue sarcoma. Phase 1 results in sarcoma patients indicated mecbotamab vedotin was generally well-tolerated in this refractory sarcoma population. Few patients discontinued due to an adverse event and no clinically meaningful on-target toxicity to normal AXL-expressing tissue was observed over baseline levels. Dose-limiting toxicities were limited to free circulating MMAE payload-associated toxicity at the highest dose tested, including reversible neutropenia. We are conducting a Phase 2 study (BA3011-002) in AXL positive NSCLC patients who have previously progressed on programmed cell death protein 1 ("PD-1")/programmed cell death ligand 1 ("PD-L1"), epidermal growth factor receptor ("EGFR"), or anaplastic lymphoma kinase ("ALK") inhibitor therapy. We are also conducting a potentially registrational Phase 2 study in sarcoma. In both Phase 2 indications, we are enrolling patients either as a monotherapy or in combination with the PD-1 inhibitor nivolumab.

Ozuriftabmab vedotin (BA3021): We are developing our second clinical stage product candidate, ozuriftamab vedotin or BA3021, a CAB antibody drug conjugate directed against ROR2, or Receptor Tyrosine Kinase Like Orphan Receptor 2. ROR2 is overexpressed across many different solid tumors, including breast, lung, pancreatic, renal, ovarian, and colorectal cancers, squamous cell cancer of the head and neck, or SCCHN, and melanoma; its tumoral expression is further enhanced among those treated with PD-1 checkpoint inhibitors. Cancer cell expression of ROR2 has been associated with enhanced cancer cell migration, EMT, increased associated risk for relapse, metastasis and unfavorable prognosis. In breast cancer, for example, ROR2 was found to be expressed in the majority of patient samples, with those expressing ROR2 having decreased overall survival. A similar correlation between ROR2 expression level and overall survival was observed in NSCLC and metastatic melanoma. Genetic inactivation of ROR2 in metastatic melanoma cells was shown to prevent metastases of these tumor cells in mice. ROR2 also

has essential roles in normal cells and in early development. Inactivation of ROR2 is lethal in mice with defects observed in the heart, nervous system and skeleton. Less severe mutations in ROR2 in humans is associated with skeletal diseases Robinow syndrome and brachydactyly type B.

Ozuriftamab vedotin is a CAB anti-ROR2 ADC consisting of a CAB anti-ROR2 humanized IgG1 monoclonal antibody conjugated to MMAE using a cleavable linker. Ozuriftamab vedotin is designed to specifically and reversibly bind to ROR2 in conditions found within the tumor microenvironment, thus conferring a selectivity binding advantage for tumors over normal cells. Upon binding of ozuriftamab vedotin to ROR2 on the surface of tumor cells, it is internalized and the MMAE cytotoxin is released, thus killing the cancer cell.

We are developing ozuriftamab vedotin as a potential therapeutic for multiple solid tumor types, including melanoma and SCCHN. Based on Phase 1 data, we believe ozuriftamab vedotin has broad potential as a cancer therapy for patients with advanced solid tumors who have experienced prior failure of PD-1 blockade. We are enrolling a Phase 2 trial of ozuriftamab vedotin monotherapy or in combination with a PD-1 inhibitor in patients with ROR2 positive melanoma who have previously progressed on PD-1/L1 inhibitor. We are also conducting a Phase 2 study in patients with SCCHN.

Evalstotug (BA3071): Our third clinical stage product candidate, evalstotug, is a CAB anti-CTLA-4 antibody that is being developed as an immuno-oncology agent with the goal of delivering at least the efficacy of approved CTLA-4 antibodies, such as ipilimumab, but with lower toxicity rate as a result of the CAB's unique tumor microenvironment-restricted binding. CTLA-4, or cytotoxic T-lymphocyte-associated antigen 4, is an immune checkpoint involved in regulating T-cell activation. The primary role of immune checkpoints is to prevent autoimmune attacks against normal tissue in the body; however, cancer cells often take advantage of this pathway to prevent immune destruction of the tumor. Ipilimumab and tremelimumab currently are the only anti-CTLA-4 monoclonal antibodies approved by the FDA. Ipilimumab is approved as a single agent for the treatment of melanoma, and in combination with an anti-PD-1 antibody for the treatment of multiple solid tumors, including melanoma, RCC, colorectal cancer and NSCLC, and tremelimumab is approved in combination with an anti-PD-L-1 antibody for the treatment of unresectable hepatocellular carcinoma and NSCLC. Patients treated with these checkpoint inhibitors face a risk of a number of adverse events associated with inappropriate activation of the immune system beyond the tumor site including severe and sometimes fatal enterocolitis, hepatitis, dermatitis, neuropathy and endocrinopathy. Consequently, usage and dosage of ipilimumab is highly limited due to its safety profile.

We are developing evalstotug as a potential therapeutic for multiple solid tumor indications. We have initiated a Phase 1/2 dose-escalation trial of evalstotug as monotherapy and in combination with an anti-PD-1 antibody. We have also initiated our Phase 2 study of evalstotug for treatment-refractory melanoma and carcinomas, and treatment-naïve melanoma and NSCLC, at a dose of 350mg and more recently 700mg. We are currently evaluating the 1000mg dose level in our Phase 1 study and potentially will in Phase 2 once Phase 1 is cleared. Patients receiving evalstotug at 700mg and 1000mg will be treated with prophylactic tocilizumab to help reduce risks associated with the release of cytokines into the blood from immune cells that have been activated by the treatment.

BA3182 (CAB-EpCAM x CAB-CD3): Our first bispecific candidate, BA3182, is being investigated in a Phase 1 study in advanced adenocarcinoma. We have leveraged our CAB technology to develop bispecific antibodies, which bind both a tumor-specific antigen and a T cell receptor using CAB antigen-binding domains. A bispecific antibody is a type of engineered antibody that can simultaneously bind two separate and unique antigens, unlike conventional monospecific antibodies that only bind to one type of target.

A common design feature for a bispecific antibody is to include a T cell engager component (*i.e.*, CD3 receptor), such that one antigen-binding domain recognizes a surface-expressed tumor antigen and the other antigen-binding domain binds to and activates CD3+ T cells. With this design, bispecific antibodies can induce potent T cell responses against tumors expressing the tumor target antigen in a simplified manner relative to even off-the-shelf or allogeneic CAR-T therapies. The first FDA-approved bispecific antibody was a T cell engager, blinatumomab, which contained antigen-binding domains for CD19, an antigen found on B-cell leukemias, and CD3, a T cell activating receptor.

There are multiple structural variants of antibodies and other antigen-binding domains being used by others to construct bispecific product candidates, some of which are being tested clinically. However, similar to CAR-T cells and blinatumomab, many of these bispecific product candidates have increased risks of generating life-threatening cytokine release syndrome and other potential adverse events due to systemic immune activation and the wide expression of EpCAM, or epithelial cell adhesion molecule.

We have applied our CAB antibody technology to develop bispecific CAB antibodies in which one or both antigen-binding domains are active only in the tumor microenvironment. An example of this approach is our BA3182 bispecific. EpCAM is a protein that is over-expressed in many cancers including carcinomas derived from colon, intestine, breast, lung and prostate. Expression of EpCAM has been extensively associated with cell growth and proliferation of both healthy and cancer cells.

EpCAM was one of the first cancer-associated antigens discovered, however in the forty years since, its clinical impact as a target for therapeutic antibodies in cancer has been limited. One of the problems with targeting EpCAM is its broad expression in the basolateral membranes of normal epithelial cells. Conventional approaches of avoiding systemic toxicities, including deliberately selecting antibodies with low affinity for EpCAM with the intention of generating some degree of selectivity for tumors that express very high levels of EpCAM, have not been successful. Bispecific constructs targeting EpCAM have also not lived up to expectations. Solitomab, an EpCAM x CD3 bispecific led to over 95% of patients in a Phase 1 dose-escalation trial to experience at least one Grade 3 or above adverse event. Over 20% of patients experienced dose-limiting toxicities, and at these required low doses, there was only one unconfirmed partial response observed among 65 patients.

We are also completing Investigational New Drug (IND) enabling studies for our next-generation CAB ADC, Nectin-4 with an expected IND in 2024. Additional in-process CAB candidates including B7 H3 x CD3 bispecific, EGFR x CD3 bispecific, Nectin4 x CD3 bispecific, and

B7-H4 as a next-generation CAB ADC candidate have been positioned for partnering and portfolio prioritization in favor of our Phase 2 potential registrational trial enabling studies.

Our strategy

Our mission is to develop and commercialize innovative antibody-based therapeutics for the treatment of solid tumors that are designed to bind depending on the physical and chemical properties of tumors and their microenvironment. We believe that our proprietary CAB technology and approach have the potential to transform cancer therapy by decreasing systemic toxicities and improving efficacy. Our strategy to achieve this mission is as follows:

- **Advance our lead product candidates through regulatory approval and commercialization.**
  - *Mecbotamab vedotin (BA3011):* Clinical data from our Phase 1 and Phase 2 part 1 trials with mecbotamab vedotin are supportive of its development in metastatic sarcomas, a set of cancers with a high unmet clinical need, and in metastatic PD-1 failure NSCLC. We are conducting a potentially registration-enabling Phase 2 trial for mecbotamab vedotin in undifferentiated pleomorphic sarcoma, or UPS, patients (12 years of age or older). In addition, we have obtained FDA clearance to initiate a potentially registration-enabling Phase 2/3 trial in NSCLC in 2nd Line + or 3rd Line + population.
  - *Ozuriftamab vedotin (BA3021):* We have observed antitumor activity in PD-1 failure NSCLC, melanoma and SCCHN patients in our Phase 1 trial and have initiated Phase 2 trials of ozuriftamab vedotin in the melanoma and SCCHN indications.
  - *Evalstotug (BA3071):* Evalstotug is designed to provide the efficacy similar to that of ipilimumab, an anti-CTLA-4 monoclonal antibody approved by the FDA, but with the potential of a significantly enhanced safety profile due to the conditional binding properties of CABs. This may allow for patients to be treated at higher dosage and/or for more cycles of treatment in combination with an anti-PD-1 antibody that may lead to better therapeutic results. To date, we have observed objective responses and disease control among patients treated in our Phase 1 study at 350mg in combination with anti-PD-1 antibody, and have seen limited adverse events of Grade 3 or higher, suggesting an improved safety profile for evalstotug.
  - *BA3182 (CAB-EpCAM x CAB-CD3)*: Our first bispecific candidate with an IND, cleared by FDA, demonstrated in its IND-enabling studies a more than 100-fold improvement in the therapeutic window. We have initiated a Phase 1 study in advanced adenocarcinoma. Carcinoma is the most common form of cancer and adenocarcinoma is the most common subtype. Adenocarcinoma is most prevalent in the lung, prostate, breast, pancreas, esophagus, colon/rectum and stomach. Almost all prostate and breast cancers are adenocarcinoma, and about 96% of colorectal and 40% of non-small cell lung cancers are adenocarcinoma (American Cancer Society 2022).
- **Enhance pre-clinical assets with multiple CAB bispecific and next generation CAB ADC candidates to further address areas of high unmet needs in treating solid tumors.** We have shown in preclinical experiments, including for our Phase 1 clinical asset, BA3182, that our CAB bispecific molecules meet or exceed the activity of conventional bispecifics and reduce systemic activation of potentially fatal immune responses. For example, BA3182 demonstrated in its IND-enabling studies a more than 100-fold improvement in the therapeutic window.

  We believe that our next generation CAB-ADC platform further widens that therapeutic window by enhancing the linker-payload system. Combining our CAB technology with our next generation CAB-ADC platform replaces the traditional peptide linker with a novel sugar-based linker to deliver the MMAE payload. It is expected that this new CAB ADC system will further reduce off-target, off-tumor toxicity and thereby expand the therapeutic window.
- **Maintain and strengthen our intellectual property portfolio.** As of February 1, 2024, we had a total of 752 patents and patent applications with 479 issued patents, 13 allowed applications and 260 pending applications covering our CAB technology and product candidates. This broad patent coverage was designed such that protection of our product candidates is not dependent on any single patent but rather, each product candidate provides multiple layers of protection. We plan to continue to maintain, monitor, enforce and defend our intellectual property.
- **Enter into collaborations to maximize the value of our platform and pipeline.** Given the potential of our technology to generate novel product candidates addressing a wide variety of solid tumors, we may opportunistically enter into strategic collaborations around specific geographic regions, indications, combinations and companion diagnostics. We may also explore collaboration arrangements to commercialize any product candidates where we believe the resources and expertise of the third party could be beneficial. These collaborations could advance and accelerate our programs to maximize their market potential and expand the worldwide commercial potential of our CAB technology and assets.

Our technology

Challenges in developing antibody-based therapies for solid tumors

Monoclonal antibody therapeutics have been approved for dozens of therapeutic targets, most commonly cancer. Antibodies have become the backbone of the pharmaceutical industry, which previously relied on small molecules. Treatment with monoclonal antibodies has established itself as one of the most successful therapeutic strategies for both hematologic malignancies and solid tumors. Oncology targets of safe, effective antibodies fall into two broad categories:

- Antibodies targeting antigens, usually proteins, preferentially expressed on the surface of cancer cells, against which antibodies are used to directly bind and inhibit or destroy these cells; and

- Antibodies targeting antigens affecting directly or indirectly tumor cells and non-tumor cells that activate the immune system or induce other changes in the tumor, such as limiting the growth of tumor-related blood vessels.

There are significant limitations of targeting important antigens with traditional antibodies that can result in reduced efficacy, difficulties related to dosing, decreased durability, and drug-related toxicities, all of which significantly limit the potential for cures with traditional antibodies:

- **Increased toxicity**: Antigens are typically expressed in many normal tissues, which for traditional antibodies, including ADCs, could lead to significant on-target, off-tumor toxicity reducing dosing and durability.
- **Target-mediated drug disposition limitation**: Target-mediated drug disposition, or TMDD, is the phenomenon in which a drug binds somewhat indiscriminately to its pharmacological target on normal tissue as well as on the intended diseased tissue, thereby causing the antibody to be depleted more rapidly from circulation. As a consequence, the pharmacokinetic characteristics of the drug can be adversely impacted, leading to reduced half-life, lower tumor exposure, which requires more frequent or higher dosing that increases toxicity and ultimately can result in undesirable side-effects, patient treatment-related inconveniences and greater costs.
- **Immunogenicity**: Antibodies also can be sensitive to modifications that can lead to immunogenicity, or a strong negative immune system response from the body, which can induce anti-drug antibodies that can reduce efficacy or lead to severe infusion reactions, thereby restricting the potential improvements that could be made with emerging technologies.

The fundamental specificity challenge with traditional monoclonal antibody-based therapy is that there are few known antigens that are specific to tumors and absent in non-cancerous tissues. Drug developers might develop an antibody that is exquisitely specific against its target, but due to the expression of the target on non-tumor cells, systemic administration can result in dose-limiting toxicities from on-target, off-tumor activity.

The majority of anticancer antibody-based drug products are consequently limited to a small subset of potential tumor antigens. We believe that our novel approach to increase the selectivity of antibody-based therapeutics while maintaining their potency may have the potential to fundamentally transform the development of anticancer therapeutics and expand the universe of targets for novel antibody-based therapies.

CAB leverages the low pH found in the tumor microenvironment

The tumor microenvironment has been widely implicated in tumorigenesis because it harbors cancer cells that interact with surrounding cytokines and cells through the circulatory and lymphatic systems to influence the development and progression of cancer. The tumor microenvironment has conditions distinct from the normal cellular and extracellular environments found in non-cancerous tissue, blood or other parts of a normal body. It has been long appreciated that the extracellular milieu inside and surrounding the growing tumor mass is distinct and unique. One of the most profound physicochemical differences between the tumor microenvironment and normal cellular microenvironment is an increase in lactic acid and an associated decrease in pH in the tumor microenvironment from the normal physiological pH of about 7.4 or higher.

While the tumor is acidic, some of the most acidic regions of tumors can be observed at the edge of the tumors, just at the interface with the surrounding tissue or blood, according to a paper published in 2019 in the journal Cancer Research. In this study, pH low insertion peptide, or pHLIP, a peptide that is taken up by cells at a pH below 6.5, was injected into human tumor-bearing mice. While nearly all tumor cells took up this peptide, normal tissue cells did not take up this peptide except in the liver and kidney, which was expected in a pH-independent manner in order to be metabolized and excreted. Certain regions within the tumor and in the cells at the edge of tumors took up some of the highest concentration of the probe, indicating that these areas had pH substantially lower than 6.5. These findings are important when considering the design of therapies for solid tumors because they point to the fact that while the overall tumor is acidic, the most accessible and rapidly growing portions of tumors are likely to have some of the lowest pHs.

One reason for the low pH in tumors compared to normal cells is that there are distinct differences in the metabolic processes found in normal and cancer cells. Normal cells generate the energy they need primarily through the oxygen-dependent process called oxidative phosphorylation. In comparison, cancer cells have switched their mechanism of energy production preferentially to the non-oxygen-dependent process known as glycolysis, even in the presence and availability of oxygen. This process switch, known as the Warburg Effect, was first described nearly a century ago and is the basis of modern tumor screening technologies, such as Positron Emission Tomography or PET scanning. The dependence of a tumor cell on glycolysis results in the tumor cell metabolizing up to 200 times more glucose than a healthy cell and causing the secretion of significant levels of lactic acid into the tumor microenvironment. This inherent buildup of lactic acid in the tumor microenvironment has been shown to reduce immune cell function and modulate other defense mechanisms of the body, promoting tumor growth and tumor survival. The presence of lactic acid in the tumor microenvironment causes it to have a distinctly acidic pH of less than 6.8 and even lower at the tumor cell surface, a pH so low that it is rarely found in the body except in organs designed for low pH, such as the stomach, where antibodies in the blood do not access, and in special circumstances, such as cancer. In some cancers, the pH goes as low as 5.8, an extremely low level given the normal, slightly alkaline, pH in the body. The body's blood holds its pH within a tight range around a pH of 7.4, with normal tissue typically being even more alkaline in the non-cancerous regions of tissues afflicted with cancer.

Tumors not only have characteristically low pH, which assists them in reducing the body's immune defenses, along with acidity they also generate other aberrant conditions and secrete other chemicals and proteins into the tumor microenvironment that can stimulate tumor growth, promote the development of new blood vessels or angiogenesis, degrade surrounding tissues allowing the tumor to spread or metastasize or actively suppress detection and destruction by the immune system. In view of our preclinical studies and clinical trial results and the substantial supporting scientific literature, we believe that there is an opportunity to develop cancer therapies with improved selectivity for tumors by taking

advantage of changes in pH, as do our existing product candidates, as well as in the conditions and levels of temperature, pressure and chemical composition in the tumor microenvironment.

Our CAB technology

Our CABs are based on our patented protein discovery and engineering technology. We invented, developed, and refined this technology, which we believe selectively enables the binding of proteins and antibodies to targeted cells in the tumor microenvironment based on differences in local conditions such as pH, temperature, or chemical composition compared to normal healthy tissue. We have shown that activity of our CAB biologics is reversible; not only are they active due to the low pH levels of the tumor microenvironment, but also, unlike prodrugs, they are reversibly inactive when they leave the tumor microenvironment and are in a normal physiological environment.

Our CAB technology capitalizes on the well-established Warburg Effect that through a glycolytic process leads to an acidic external tumor microenvironment. Extracellular pH levels in tumors have been measured to be as low as pH 5.8 compared to the tightly controlled, alkaline, pH 7.4 of blood, with even higher pH in healthy tissues. Glycolytic metabolism is also the basis of the established PET scanning technology for detection of cancerous tumors. CAB proteins have increased binding activity as the pH in the microenvironment becomes acidic, while being inactive in normal physiological environments. We discovered a novel chemical switch mechanism that underpins this binding activity that involves physiologically occurring chemicals, such as bicarbonate and hydrogen sulfide. These molecules are negatively charged at physiological conditions and interact with positive charged areas on the protein surface. Under acidic conditions found in the tumor microenvironment, these charged molecules are neutralized by the H+ ions and released from the protein surface, uniquely allowing CAB antibodies to bind to their target and attack the tumor cell. We refer to this novel physiological mechanism, used for generating CABs, as Protein-associated Chemical Switch(es)™ or PaCS™ mechanism. The ability to design conditionally active therapeutics with strong selectivity over narrower pH ranges using the PaCS mechanism, offers the opportunity to greatly enhance both the safety and potency of future therapies for solid tumors.

We have used and continue to leverage our patented CAB technology to screen antibody candidates for multiple characteristics. By doing so, we can evolve specific regions on the antibody that will only bind in response to environmental conditions, either enhancing or eliminating binding. Our CAB technology allows us to select antibodies that preferentially bind to the target under the conditions of interest, such as high local acidity (i.e. low pH). CAB antibodies have human or humanized antibody sequences, a characteristic that reduces the risk of immunogenicity compared to emerging technologies in the field, which is supported by both our preclinical and clinical data.

Our CAB antibodies have been designed to be active in the acidic, lower pH of the tumor microenvironment and inactive under the alkaline pH of 7.4 and above found in normal physiological conditions. In a quantitative *in vitro* binding assay, we compared a CAB antibody and a non-CAB antibody that both bind to the target AXL with matched strength of binding to the target, or affinities, when measured at pH 6.0. The binding of the CAB antibody was highly sensitive to pH with binding becoming much weaker as it approached pH 7.0 and almost undetectable at a physiological pH of 7.4. In contrast, a non-CAB antibody to AXL showed indiscriminate and experimentally equivalent binding across the entire pH range tested, including at pH 7.4 of normal cells. Our CAB development process is capable of identifying CAB antibodies with a range of sensitivities to pH.

Low pH-dependent CAB antibodies are far less likely to bind to targets outside of tumors, resulting in a number of potential advantages over traditional antibodies:

- **Wide therapeutic window.** Reduced binding to target antigens outside of the tumor has the potential to reduce toxicities that arise from systemic exposure. We believe this may enable higher doses or increased potency to be safely delivered to patients with the potential for increased efficacy.
- **Opportunity to increase tumor-specific killing.** The wide therapeutic window imparted by tumor-specific targeting enables CAB antibodies to be modified with cytotoxic drugs to create ADCs. Similarly, bispecific antibodies can be developed using CAB antibody domains targeting pairs of targets that direct T cells to attack the tumor, thereby reducing the likelihood of unacceptable normal tissue injury if constructed using traditional antibody domains.
- **Increased drug exposure to tumors.** Limited binding to targets outside of tumors allows more of the administered CAB antibodies to be available to bind to target sites in the tumor, potentially increasing the concentrations and exposure of these antibodies in tumors.
- **Improved pharmacokinetics.** Limited binding to targets outside of tumors effectively increases their half-life in plasma. The phenomenon of TMDD, is a well-known limitation facing the development of many biologics which CAB antibodies can significantly reduce.
- **Broader universe of tumor-specific antigens that can be targeted.** There are few highly prevalent tumor-specific antigens expressed on solid tumors that are not expressed at some level in normal tissues, particularly for solid tumors, which represent approximately 90% of tumor types. While some targets, such as EGFR, can be targeted by traditional antibodies with some acceptable level of toxicity in a subset of patients, many other potential targets cannot. CAB antibodies with pH-dependent binding have the potential to significantly reduce the potential risk of systemic toxicities caused by expression of targets on normal tissues.

We have developed CAB antibodies through the use of our proprietary technology, which we believe have specificity for tumors, while avoiding binding to the same antigen target expressed on many normal tissues. This allows us to develop therapeutics against targets that are expressed at high levels on tumor cells but are also present on normal cells and tissues, without the toxicities associated with traditional antibodies. While our lead product candidates primarily exploit the differences in pH between the tumor microenvironment and healthy tissue, there is a potential for other yet to be identified PaCS molecules in disease related microenvironments, whether controlled through pH,

concentration, or other molecular characteristics (intra- or intermolecularly) for enhancing a drug's therapeutic index. Potential new therapeutic candidates addressing these opportunities are not limited to antibodies, but may also include small molecules, encompassing lipids, sugars and nucleic acid-based agents or drugs. Further, it is expected that PaCS protein-chemical systems are important naturally occurring regulatory systems linked to a range of disease-related microenvironments, including cancer, inflammation and cellular senescence.

Programs in clinical development

Mecbotamab Vedotin (BA3011) targeting AXL

Phase 1 clinical trial

We have conducted a Phase 1 trial of mecbotamab vedotin in patients with advanced solid tumors, including sarcoma, pancreatic cancer, adenoid cystic carcinoma (ACC), and NSCLC who were refractory or resistant to standard therapies. In the Phase 1 trial, patients were treated with doses of mecbotamab vedotin ranging from 0.3 mg/kg to 3 mg/kg once every three weeks (Q3W) or doses ranging from 1.2 mg/kg to 1.8 mg/kg twice every three weeks on days 1 and 8 (2Q3W).

The main goals of this trial were to evaluate the safety, tolerability, antitumor activity, pharmacokinetics and immunogenicity of mecbotamab vedotin in solid tumor patients. Based upon the overall safety and response rates, the initial recommended Phase 2 dose was determined to be 1.8 mg/kg delivered every two weeks (Q2W).

In the Phase 1 studies, mecbotamab vedotin was generally well-tolerated. Grade 3 or greater adverse events, or AEs, or serious adverse events, or SAEs, deemed related to mecbotamab vedotin were consistent with MMAE-based toxicity and could generally be classified as either reversible myelosuppression (AEs: neutropenia and anemia), transient liver enzyme elevations (AEs: aspartate aminotransferase ("AST")/ alanine aminotransferase ("ALT") increased) or metabolic disturbances (AEs: hyperglycemia, hyponatremia, hypokalemia).

We have not observed adverse events that appear to be related to on-target injury of normal, AXL expressing tissues, i.e., on-target, off-tumor toxicity, consistent with the increase in tumor selectivity from the CAB technology. The estimated half-life of mecbotamab vedotin was approximately four days.

Phase 2 Clinical Development

UPS Phase 2 trial:

We are conducting a Phase 2, single-arm, potentially registration-enabling trial with mecbotamab vedotin monotherapy in patients with UPS who have experienced prior treatment failure. We believe UPS represents a critical unmet need and we are exploring accelerated approval options for patients otherwise suffering from uncontrolled sarcoma with few effective treatment options. While it is acknowledged that a randomized confirmatory trial is typically employed to confirm clinical benefit. Given the marked rarity of UPS patients, it may be possible, subject to future agreement with the FDA, to confirm clinical benefit by enrolling additional UPS patients in a prospective clinical trial with the purpose of providing regulators with extended follow-up that adequately characterizes disease control and overall tolerability. A variety of trial options are under consideration to meet anticipated requirements associated with confirmation of clinical benefit.

The open-label, two-part Phase 2 trial evaluates the efficacy and safety of mecbotamab vedotin alone and in combination with an anti-PD-1 agent in adult and adolescent patients, and advanced, refractory measurable sarcoma. Patients received either mecbotamab vedotin alone or in combination with an anti-PD-1 agent. Part 1 antitumor activity has exceeded predefined criteria for advancing trials for UPS, osteosarcoma, liposarcoma, synovial sarcoma, chondrosarcoma, and chordoma. Part 1 of the trial employing the 1.8 mg/kg dose delivered every other week is now fully enrolled, and a clinical update was presented as an oral presentation at the ESMO Sarcoma and Rare Cancers Congress in March 2024.

As noted above, our ongoing Phase 2, part 2, potentially registrational trial employing the 1.8 mg/kg dose delivered on days 1 and 8 of a three-week cycle (2Q3W) is enrolling patients with locally advanced unresectable or metastatic UPS. Primary endpoints include overall response rate (ORR), AEs, SAEs, and changes from baseline in laboratory parameters and vital signs. Key secondary endpoints include duration of response (DOR), progression-free survival (PFS), best overall response (BOR), disease control rate (DCR), time to response (TTR), progression-free rate (PFR) at 12 weeks, overall survival (OS), and percent change from baseline in tumor size.

Patients must have measurable disease by Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1. Additionally, patients must have received no more than three prior systemic regimens. Enrolled patients are receiving open-label mecbotamab vedotin treatment.

A planned interim analysis will be performed after all patients in Phase 2, part 2 have an opportunity to be followed for at least 12 weeks. Efficacy, safety, and an integrated PK and exposure-response analysis will be performed based on all UPS patients in Phase 1, Phase 2 part 1, and the UPS patients initially enrolled in Phase 2 part 2.

NSCLC Phase 2 trial:

This ongoing multi-center, open-label, Phase 2 study is designed to evaluate the efficacy and safety of mecbotamab vedotin alone and in combination with an anti-PD-1 agent in patients with metastatic NSCLC who have measurable disease by RECIST v1.1 criteria. Enrolled patients must have had prior disease progression on a PD-1/L-1 inhibitor. Patients with EGFR or anaplastic lymphoma kinase (ALK) genomic tumor aberration had to have disease progression on FDA-approved therapy for these aberrations. Patients receive either mecbotamab vedotin alone or in combination with an anti-PD-1 agent. Primary endpoints include overall response rate, AEs, SAEs, and changes from baseline in laboratory parameters and vital signs. Key secondary endpoints include DOR, PFS, BOR, DCR, TTR, PFR at 12 weeks, OS, and percent change from baseline in tumor size.

Ozuriftamab Vedotin (BA3021) targeting ROR2

Phase 1/2 clinical trial

A Phase 1/2 single-arm clinical trial of ozuriftamab vedotin monotherapy in patients with locally advanced unresectable or metastatic solid tumors in melanoma is being conducted. Patients were treated with doses of ozuriftamab vedotin ranging from 0.3 mg/kg to 3.3 mg/kg once every three weeks (Q3W) or doses ranging from 1.5 mg/kg to 1.8 mg/kg twice every three weeks on days 1 and 8 (2Q3W). Based upon the overall safety and response rates, the initial recommended Phase 2 dose was determined to be 1.8 mg/kg delivered every two weeks (Q2W).

In the Phase 1 component of the trial, treatment with ozuriftamab vedotin resulted in multiple responders in patients with treatment-refractory solid tumors, including melanoma, NSCLC, and head and neck cancer. All of these patients had previously progressed following PD-1 therapy.

Similar to mecbotamab vedotin, ozuriftamab vedotin continues to be generally well-tolerated. We have not observed adverse events that appear to be related to on-target injury of normal, ROR2-expressing tissues. We believe that reported toxicities were consistent with off-target effects of free MMAE consistent with those described with other marketed MMAE-based ADCs.

In the Phase 1 trial, the Grade 3 or greater AEs or SAEs deemed related to ozuriftamab vedotin were consistent with MMAE-based toxicity and could generally be classified as either reversible myelosuppression (AEs: neutropenia, anemia), transient liver enzyme elevations (AEs: AST/ALT increased) or metabolic disturbances (AEs: hyperglycemia, hyponatremia, hypokalemia).

Phase 2 Clinical Development

A Phase 2 open-label trial to evaluate the efficacy and safety of ozuriftamab vedotin alone and in combination with an anti-PD-1 agent in patients who have experienced prior disease progression on a PD-1/L1 inhibitor is ongoing in melanoma who have measurable disease. Primary endpoints include ORR, AEs, SAEs, and changes from baseline in laboratory parameters and vital signs. Key secondary endpoints include DOR, PFS, BOR, DCR, TTR, PFR at 12 weeks, OS, and percent change from baseline in tumor size.

We have also completed enrollment for a Phase 2 clinical trial of ozuriftamab vedotin as monotherapy in SCCHN using 1.8mg/kg with either Q2W or 2Q3 dosing. Primary endpoints include overall response rate, AEs, SAEs, and changes from baseline in laboratory parameters and vital signs. Key secondary endpoints include DOR, PFS, BOR, DCR, TTR, PFR at 12 weeks, OS, and percent change from baseline in tumor size.

Evalstotug (BA3071) targeting CTLA4

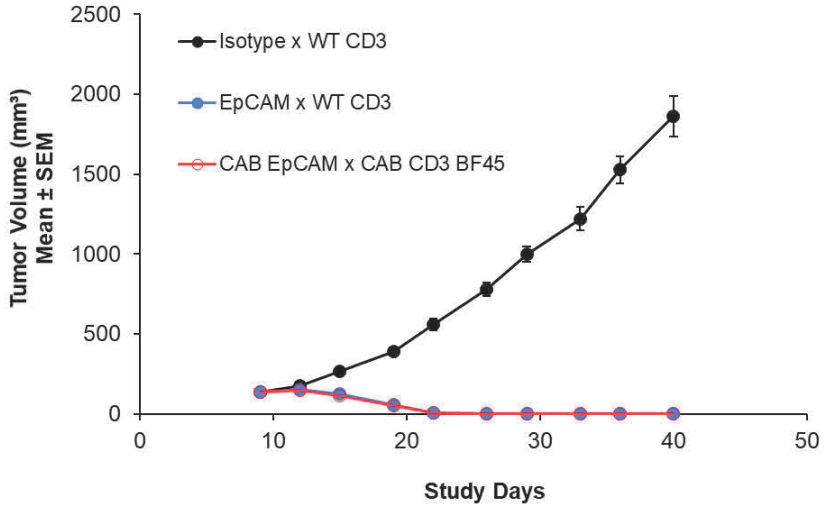
The Phase 1 dose-escalation trial of evalstotug in advanced solid tumor patients continues enrollment in the dose-escalation portion of the trial. We are evaluating the safety and tolerability of evalstotug at doses ranging from 7mg Q3W to 1000mg Q3W as monotherapy and in combination with an anti-PD-1 antibody. A Phase 2 open-label trial to evaluate the efficacy and safety of evalstotug alone and in combination with an anti-PD-1 agent, and also in combination with chemotherapy for 1st Line NSCLC, in patients who have treatment-refractory melanoma and carcinoma and who have treatment-naïve metastatic melanoma and NSCLC is underway. To date, we have observed limited adverse events of Grade 3 or higher in our Phase 1 study at 350mg in combination with PD-1 suggesting an improved safety profile for evalstotug. Prior to seeking accelerated approval for any proposed indication, we will seek feedback from the FDA and evaluate our ability to obtain accelerated approval. If acceptable, we plan to submit our proposed confirmatory trial design for FDA feedback and commence enrollment prior to our Biologics License Application ("BLA") submission.

BA3182 (CAB-EpCAM x CAB-CD3)

We are conducting a Phase 1 study designed to evaluate the safety, tolerability, pharmacokinetics, immunogenicity, and antitumor activity of BA3182, a conditionally active biologic (CAB)-bispecific T-cell engager antibody construct targeting EpCAM in patients with advanced adenocarcinoma.

BA3182 is designed with an EpCAM binding domain and a CD3 binding domain, both binding domains with CAB activity (Dual-CAB). In our preclinical studies, we showed that a dosage of 1mg per kilogram of this construct twice per week in mice, which is roughly equivalent to

0.25 mg per kilogram in non-human primates, had a potent antitumor activity in a HCT116, a human colorectal carcinoma cell line, xenograft model in mice with a humanized immune system.



Preclinical safety findings

While there was no observable difference in antitumor efficacy between antibodies with CAB domains and those with conventional non-CAB antigen-binding domains, a conventional EpCAM x CD3 bispecific antibody led to a much higher level of undesirable systemic immune activation than the CAB-EpCAM x CAB-CD3 (BA3182) bispecific antibody in non-human primates.

Preclinical candidates

BA3361 (CAB-Nectin-4-ADC)

Nectin-4 is widely expressed and has adhesive roles in normal tissues. The CAB selectivity to target Nectin-4 in the tumor microenvironment is critical in providing the necessary safety to deliver the drug conjugate selectively to cancerous tissue. A clinical candidate was selected from a set of lead molecules that were characterized by multiple assays including functional assays. In addition to the assay performance, the lead candidate demonstrated high binding under tumor conditions and little to no binding under normal physiological conditions. We plan to submit an IND for BA3361 in 2024.

BA3151 (CAB-B7-H4-ADC)

B7-H4 is highly expressed on numerous tumor tissues and the expression level directly correlates with adverse clinical and pathological features. A set of lead molecules were characterized *in vitro* including functional assays and *in vivo* efficacy models. Selection of the lead candidate was based on criteria including high binding activity under tumor conditions and low binding activity under normal physiological conditions.

BA3142 (CAB-B7-H3 x CAB-CD3)

We believe that our CAB technology opens up the opportunity for the creation of a broad set of bispecific product candidates with antitumor potential. Through these CAB bispecific antibodies, we believe we can activate T cells directly in tumors using CAB domains targeting tumor-specific antigens. We believe our CAB bispecific antibodies may allow for increased efficacy through more potent T cell activation, higher doses or administration in combination with other immuno-oncology therapies, such as checkpoint inhibitors. We have shown in preclinical experiments that our CAB bispecific molecules meet or exceed the activity of conventional bispecifics and reduce systemic activation of potentially fatal immune responses. In February 2023 we received from the FDA clearance of our IND application to evaluate our CAB bispecific antibody product candidate BA3182, which is now part of an ongoing Phase 1/2 clinical study.

Our second bispecific product candidate, BA3142, is a dual-CAB T-cell engager targeting B7-H3, a protein expressed on many solid tumors. The lead molecule was characterized by multiple assays including functional assays, and by efficacy studies in a xenograft model of human pharyngeal cancer using mice with a humanized immune system. The lead molecule showed antitumor activity comparable to a non-CAB antibody, while demonstrating lower binding and functional activity under physiological conditions, as expected for a CAB bispecific antibody. Cell line development and *in vivo* efficacy study are completed.

CAB-EGFR bispecific programs

Targeting EGFR with a CAB bispecific antibody is expected to provide benefit since the target is widely expressed in healthy tissue, such as skin, which would otherwise result in on-target, off-tumor toxicity if targeted by a non-CAB antibody. A set of lead molecules were

characterized by multiple assays including functional assays and all demonstrated high activity at acidic pH with little to no activity under physiological conditions. Two molecules are in development: a mono-CAB (EGFR x CAB-CD3) and a dual-CAB (CAB-EGFR x CAB-CD3).

BA3362 (CAB-Nectin 4 x CAB-CD3)

BA3362 is a dual CAB bispecific product candidate. The cell line development and *in vivo* efficacy study are completed. Non-GLP toxicology study in cynomolgus monkeys is in progress.

Competition

The biotechnology and biopharmaceutical industries, including the oncology subsector, are characterized by rapid evolution of technologies, competition and strong defense of intellectual property. Any product candidates that we successfully develop and commercialize may have to compete with existing therapies and new therapies that may become available in the future. While we believe that our patented technology platform, intellectual property, know-how and scientific expertise in the field of biologics and immuno-oncology provide us with certain competitive advantages, including the ability of our product candidates to be active under conditions representative of the tumor microenvironment and not in normal cell conditions, we face potential competition from a wide variety of institutions, including large biopharmaceutical companies, specialty biotechnology companies, academic research departments and public and private research institutions. In immuno-oncology, we face substantial competition in the form of competing approaches to targeted antibody therapy in general, as well as competing treatments for the same types of cancer that we would plan to address with our pipeline of product candidates.

There are several companies in various stages of clinical development of ADCs, one of the key features of our product candidates mecbotamab vedotin and ozuriftamab vedotin. Currently, there are multiple approved ADCs and many more in clinical development, the vast majority of which are being developed for the treatment of cancer. Certain other companies are also pursuing antibody therapies in immuno-oncology. Although we do not believe competing companies have selective CAB technology, there is a wide array of activity in multiple areas of immune-based cellular therapies for oncology.

In addition, if any of our product candidates are approved in oncology indications such as pancreatic, breast and other cancers, they may compete with existing biologics and small molecule therapies, or may be used in combination with existing therapies. There are also many other therapies under development that are intended to treat the same cancers that we are targeting or, although yet to be identified, may target with our CAB technology platform, including through approaches that could prove to be more effective, have fewer side effects, be cheaper to manufacture, be more convenient to administer or have other advantages over any products resulting from our technology.

Many of our competitors, either alone or with strategic partners, have substantially greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive. Accelerated merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. In addition, our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Manufacturing

Our CAB antibodies are designed and produced using our patented Comprehensive Integrated Antibody Optimization™, or CIAO!™, technology. The successful evolution, design, and development of a CAB antibody with specific characteristics and qualities require that the development and manufacturing processes result in the CAB antibody with the desired properties. We have developed our patented process of CIAO! that integrates into the design process the critical features for subsequent development steps and manufacturing. A key element of the CIAO! process is that all design and development of the antibody is conducted in a mammalian cell line such as Chinese hamster ovary. This host cell is essentially identical to that used for manufacturing the majority of antibodies. This integrated and efficient approach is designed to provide consistency of the folding, glycosylation and other critical features throughout the development and commercialization process for improved activity, selectivity and yields in manufacturing.

We currently do not own or operate any manufacturing facilities. We rely, and expect to continue to rely for the foreseeable future, on third-party contract manufacturing organizations to produce our product candidates for preclinical and clinical testing, as well as for commercial manufacture if our product candidates receive marketing approval. We also expect to rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that require such tests. Furthermore, the raw materials for our product candidates may be sourced, in some cases, from a single-source supplier. As part of the manufacture and design process for our product candidates, we rely on internal, scientific and manufacturing know-how and trade secrets and the know-how and trade secrets of third-party manufacturers. We also contract with additional third parties for the filling, labeling, packaging, storage and distribution of investigational drug products. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our product candidates. We maintain agreements with our manufacturers that include confidentiality and intellectual property provisions to protect our

proprietary rights related to our product candidates. We have personnel with significant technical, manufacturing, analytical, quality, including current good manufacturing practices, or cGMPs, and project management experience to oversee our third-party manufacturers and to manage manufacturing and quality data and information for regulatory compliance purposes.

Collaborations

We intend to selectively enter into collaborations with preclinical and/or clinical assets, particularly where potential collaborators can both accelerate and maximize a therapeutic's market potential.

License Agreements and Strategic Collaborations

Collaboration and Supply Agreement with Bristol-Myers Squibb

On January 5, 2022, we and Bristol-Myers Squibb Company ("BMS") entered into a clinical trial collaboration and supply agreement (the "BMS Agreement"). Under the terms of the BMS Agreement, BioAtla and BMS will collaborate on clinical trials of separate combination therapies using two of BioAtla's CAB ADCs, mecbotamab vedotin (BA3011) and ozuriftamab vedotin (BA3021), each in combination with Opdivo® (nivolumab), BMS' proprietary anti-PD-1 monoclonal antibody product. We serve as the study sponsor of the scheduled studies and are responsible for costs associated with the trial execution. BMS provides Opdivo® clinical drug supply at no cost for the combination study trials. After the completion of the combination therapy trials, we are obligated to provide BMS with a final report of the data resulting from the trial. The BMS agreement was amended in October 2022 to include additional territories for our combination study trials for mecbotamab vedotin and ozuriftamab vedotin.

Global Co-Development and Collaboration Agreement with BeiGene, Ltd.

In April 2019, we entered into a Global Co-Development and Collaboration Agreement with BeiGene, Ltd. which, as amended in December 2019 and October 2020, provided for the development, manufacturing and commercialization of BioAtla's investigational CAB CTLA-4 antibody, evalstotug (BA3071). Under the terms of our BeiGene collaboration, BeiGene was generally responsible for developing evalstotug and for global regulatory filings and commercialization. We received a total of $25 million in payments from BeiGene.

On November 19, 2021, we entered into Amendment No. 3 to the Global Co-Development and Collaboration Agreement ("Amendment No. 3"). Under Amendment No. 3, the collaboration agreement was terminated, subject to survival of certain provisions, and BeiGene handed back rights to certain know-how and materials received under the collaboration agreement and we assumed responsibility for the development and commercialization of evalstotug, in addition to other standard provisions. As consideration for Amendment No. 3, we agreed to pay BeiGene mid-single digit royalties on sales worldwide and on a limited basis will share in any upfront and milestone payments received through a sublicense of evalstotug.

Amended and Restated Exclusive Rights Agreement with Himalaya Therapeutics SEZC

In January 2020, we entered into an Amended and Restated Exclusive Rights Agreement with Himalaya Therapeutics SEZC. Under the terms of the agreement, we granted Himalaya Therapeutics SEZC an exclusive, sublicensable license under certain patents and know-how controlled by us to develop, manufacture, conduct clinical trials, obtain regulatory approval of and commercialize 10 CAB-antibodies for the territory of the People's Republic of China, Macao, Hong Kong and Taiwan and a CAB-HER2-bispecific-antibody worldwide, in each case in the field of the treatment of cancer in humans. We also granted Himalaya Therapeutics SEZC an exclusive, sublicensable license under certain patents and know-how controlled by us to develop, manufacture, conduct clinical trials, obtain regulatory approval of and commercialize an IL-22 non-CAB-antibody worldwide, which option rights are subject to certain co-development plans in the agreement for the joint development and commercialization of the IL-22 non-CAB-antibody by Himalaya Therapeutics SEZC and us. The term of the agreement continues unless terminated by mutual written consent of the parties and also contains customary provisions for termination by either party. Payments to us may include upfront payments, milestone payments and royalties equal to the lower of (i) the low teens of annual net sales and (ii) the mid-twenties of the royalties and other comparable payments received by Himalaya Therapeutics SEZC from third parties, which represent a variable interest held by us, but no payments have been made to date. The royalty term, on a product-by-product and country-by-country basis, is the period of time commencing on the first commercial sale of such product in such country and expiring upon the latest of (i) the expiration of the last valid claim in a patent covering the composition of matter or method of use for such product licensed under the agreement in such country, (ii) the expiration of any other exclusivity protection of such licensed product in such country, and (iii) the 15th anniversary of the date of first commercial sale of such product in such country. We are eligible to receive up to $77.5 million in upfront payments and potential milestones.

Intellectual property

Since inception, we have recognized the value of strong, defensible and relevant intellectual property protection. We seek to protect our technologies and products and the potential market for such technologies and products. To accomplish this goal, we apply for patents covering our processes and compositions. We also apply for patents covering developments and technologies for purpose of preventing third parties from developing competing products. Inventions related to various aspects of our core technologies have already been protected by issued and pending patent applications. As of February 1, 2024, we had 752 patents and patent applications with 479 issued patents, 13 allowed applications, and 260 pending applications.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty of the invention, the obviousness of the invention and the ability to satisfy the enablement and written description requirements of the patent laws. We file all relevant types of patent applications to protect our intellectual property, including patent applications with claims directed to our processes and products, and applications and uses thereof.

We file our applications with the U.S. Patent and Trademark Office (the "USPTO") to establish a priority filing date. Generally, we initially file provisional applications. Provisional applications are designed to provide a lower-cost first patent application filing in the United States. Corresponding non-provisional patent applications must be filed not later than 12 months after the filing date of the first provisional application filed for an invention. In some cases, multiple provisional applications have been filed within a 12-month period to capture incremental developments within the 12-month priority period while obtaining an early filing date for each development. The corresponding non-provisional patent applications benefit from the provisional applications(s) since the priority date(s) of these non-provisional patent applications is/are the earlier provisional application filing date(s), and because the patent term of the finally issued patents are calculated from the later, non-provisional patent application filing dates. This system allows us to obtain an early priority date, add material to the patent application(s) during the priority year, obtain a later start to the patent term and delay prosecution costs, which may save costs in the event that we decide not to pursue examination in an application.

Subsequently, when appropriate, we pursue patent applications in foreign countries. The Patent Cooperation Treaty ("PCT") system for filing international patent applications is used. This system allows a single application to be filed within 12 months of the original priority date of the patent application designating all 157 PCT member states (including countries in South, Central and North America, Africa, Europe, Asia and Australia) in which national/regional patent applications can later be pursued based on the international patent application filed under the PCT. At the end of a period of 2 1/2 years from the first priority date of the PCT patent application, separate patent applications can be pursued in any of the 157 PCT member states either by direct national filing or, in some cases, by filing through a regional patent organization such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial cost savings where applications are abandoned within the first 2 1/2 years of filing.

We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to ensure that maximum patent coverage and value are obtained for our processes, and compositions, given existing patent office rules and regulations. Further, pending patent claims may be modified during patent prosecution to meet our intellectual property and business needs.

We also perform non-infringement searches and analyses for our existing technologies and will continue to do so for future commercial processes and products. For our new developments, we regularly perform expert searches and reviews, and monitor patents and patent applications by third-party competitors. Our policy of avoiding patent infringement is diligently executed. To the best of our knowledge as of the date of this Annual Report on Form 10-K, we have freedom to operate on all of our technologies and product candidates.

The patent positions of biotechnology and biopharmaceutical companies like ours are generally uncertain and involve complex legal, scientific and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and the scope of an issued patent can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties. For a more comprehensive discussion of the risks related to our patents, please see "Risk factors—Risks related to our intellectual property."

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 patent application related to the patent. A U.S. patent may be accorded a patent term adjustment, or PTA, under certain circumstances to compensate for delays in granting the patent caused by the United States 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 related to the U.S. patent. In addition, in the United States, the term of a U.S. patent that covers an FDA-approved drug may be eligible for a 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 regulatory 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 United States, will agree with our assessment of whether such extensions should be granted, and, if granted, the length of such extensions.

We further own trade secrets relating to our technology platform and product candidates, and we maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us are to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees and consultants also provide that all inventions conceived by the employee in the course of employment or work with us or from the employee's or consultant's use of our confidential information are our exclusive property. For a more comprehensive discussion of the risks related to our trade secrets, please see "Risk factors—Risks related to our intellectual property."

Company-owned patents

Mecbotamab vedotin is covered by a number of filings, including a published PCT application filed in 2017 that entered the national phase in 2018. Applications have been granted in Australia, Israel, Japan, Korea, Mexico, Singapore, Taiwan, and the United States and are pending in 13 jurisdictions, including most major market countries. Composition of matter claims issuing from this application would not expire before 2037.

Ozuriftamab vedotin is covered by a number of filings, including a published PCT application filed in 2017 that entered the national phase in 2018. Applications have been granted in Europe, Japan, Mexico, and the United States and are pending in 14 jurisdictions, including most major market countries. Composition of matter claims issuing from this application would not expire before 2037.

Evalstotug is covered by a number of filings, including a published PCT application filed in 2019 that entered the national phase in 2021. Applications have been granted in Australia, Israel, Korea, New Zealand, and the United States and are pending in 18 jurisdictions, including most major market countries. Composition of matter claims issuing from this application would not expire before 2039.

Our CAB-anti-EpCAM antibody and our preclinical stage CAB-anti-Nectin-4 antibody, are covered by a number of filings. As of March 1, 2023, CAB-anti-EpCAM antibodies are covered by 13 national phase filings, including the United States, and a non-PCT filing in Taiwan. As of March 1, 2023, CAB-anti-Nectin-4 antibodies are covered by 13 national phase filings and an application in Taiwan. Composition of matter claims issuing from these applications would not expire before either 2040 or 2041.

Core components of our product candidates are protected by company-owned platform applications directed to novel methods of protein evolution, methods of making conditionally active biologics, integrated selection and evolution of antibodies and proteins in expression production hosts, multi-specific antibodies and methods of making, modified antibody regions, conditionally active biological proteins, proteins targeting orthologs, discovery of and production of conditionally active biologic proteins in eukaryotic cell production hosts, conditionally active chimeric antigen receptors for modified T-cells, diagnostics using conditionally active antibodies, conditionally active polypeptides, antibodies targeted to senescent cells, conditionally active proteins for neurodegenerative diseases, and conditionally active proteins with pH selectivity. We also have 27 issued U.S. patents covering various aspects of the manufacturing methods used to generate CAB antibodies that have patent terms expiring from 2030 to 2038, excluding in potential patent term extensions.

Out-licensed patents

Himalaya Therapeutics SEZC has exclusive rights to patents/patent applications in China, Macao, Hong Kong and Taiwan relating to ROR2 (patent application 2017800294276 (China) and patent application 106115891 (Taiwan), both titled "Anti-ROR2 antibodies and their immunoconjugates and uses thereof") and relating to AXL (patent applications 201780023876X (China) and patent application 106112687 (Taiwan), both titled "Anti-AXL antibodies and their immunoconjugates and uses thereof"). Additionally, Himalaya Therapeutics SEZC has exclusive worldwide rights to patents/patent applications relating to IL-22 (Patent applications 108119613 and PCT/US19/35395, both titled "Anti-IL-22 antibodies, antibody fragments and their immunoconjugates and uses thereof") and relating to HER2 (patent application USP 62/964,747 titled "Conditionally active anti-HER2 antibodies").

BioAtla Holdings, LLC has exclusive worldwide rights to all patents for the field of adoptive cell immunotherapy "ACT" (chimeric antigen receptor (CAR) T-cell ("CAR-T")), excluding the targets licensed to EXUMA Biotech Corp ("EXUMA").

Inversagen, LLC has exclusive worldwide rights to all patents solely in the field of diseases associated with aging (outside of cancer), diagnostics related thereto and an immuno-oncology antibody.

EXUMA has an exclusive worldwide license to all patents solely to develop, make, have made, use, sell, have sold, offer for sale and import CAR-T products to four named targets for the treatment of cancer. EXUMA's rights under the agreement exclude the right to grant sublicenses to third parties to discover, develop or manufacture any CAB ACT or any component of our CAB ACT technology, except as used in or incorporated into EXUMA's ACTs for cancer.

Government regulation and product approval

Government authorities in the United States, at the federal, state and local level and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biological product candidates such as those we are developing. 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 and we may not be able to obtain the required regulatory approvals.

Licensure and regulation of biologics in the United States

In the United States, the FDA regulates biologic products under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the Public Health Service Act, or the PHSA, and regulations and guidance implementing these laws. The FDCA, PHSA and their corresponding regulations, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacturing, safety, purity, potency, labeling, packaging, storage, record keeping, approval, distribution, post-approval monitoring and reporting, sampling, import, export, advertising and other promotional practices involving biologic products. Biological products used for the prevention, treatment or cure of a disease or condition of a human being are subject to regulation under the FDCA, except the section of the FDCA that governs the approval of new drug applications, or NDAs. Biological products are approved for marketing under provisions of the PHSA, via a BLA. However, the application

process and requirements for approval of BLAs are very similar to those for NDAs, and biologics are associated with similar approval risks and costs as drugs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending NDAs or BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

U.S. biologic products development process

Biological product candidates must be approved by the FDA pursuant to a BLA before they may be legally marketed in the United States. The process generally involves the following:

- Completion of extensive preclinical laboratory tests and *in vivo* studies in accordance with the FDA's current good laboratory practice, or GLP, regulations and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- Submission to the FDA of an IND, which must become effective before clinical trials may begin;
- Approval by an independent institutional review board, or IRB, reviewing each clinical site before each clinical trial may be initiated;
- Performance of adequate and well-controlled clinical trials in accordance with the FDA's IND regulations, good clinical practice ("GCP") requirements, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biologic product candidate for its intended use;
- Preparation and submission to the FDA of a BLA for marketing approval that includes substantial evidence of safety, purity and potency from results of nonclinical testing and clinical trials;
- A determination by the FDA within 60 days of its receipt of a BLA to file the application;
- Satisfactory completion of FDA pre-approval inspections of the manufacturing facility or facilities where the biologic product candidate is produced to assess compliance with cGMPs and to assure that the facilities, methods and controls are adequate to preserve the biologic product candidate's identity, safety, strength, quality, potency and purity;
- Satisfactory completion of any potential FDA audits of the nonclinical and clinical trial sites that generated the data in support of the BLA to assure compliance with GCPs and integrity of the clinical data;
- Payment of user fees for FDA review of the BLA;
- Review of the product by an FDA advisory committee, if applicable;
- FDA review and approval of the BLA.

Preclinical studies

Before testing any biologic product candidate in humans, the product candidate must undergo rigorous preclinical testing. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as *in vivo* animal studies to assess the potential safety and activity of the product candidate and to establish a rationale for therapeutic use. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

Clinical trials under an IND

Clinical trials involve the administration of the biologic product candidate to healthy volunteers or patients under the supervision of qualified investigators, who are generally physicians not employed by, or under, the control of the trial sponsor. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors and (iii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated in the trial. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers items such as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject, or his or her legal representative, reviews and approves the study protocol, and must monitor the clinical trial until completed.

Clinical trials typically are conducted in three sequential phases that may overlap or be combined:

- **Phase 1.** The biologic product candidate initially is introduced into a small number of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution or excretion. If possible, a Phase 1 clinical trial may also seek to gain an early understanding of the product candidate's effectiveness. In the case of some product candidates for severe or life-threatening diseases, especially when the product candidate may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- **Phase 2.** The biologic product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate a particular indication and to determine dosage tolerance, optimal dosage and dosing schedule. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- **Phase 3.** The biologic product candidate is administered to an expanded patient population at multiple sites to further evaluate dosage, to demonstrate efficacy and safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and labeling. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of a biologic.

These phases may overlap or be combined. For example, a Phase 1/2 clinical trial may contain both a dose-escalation stage and a dose-expansion stage, the latter of which may confirm tolerability at the recommended dose for expansion in future clinical trials (as in traditional Phase 1 clinical trials) and provide insight into the antitumor effects of the investigational therapy in selected subpopulation(s).

Typically, during the development of oncology therapies, all subjects enrolled in Phase 1 clinical trials are disease-affected patients and, as a result, considerably more information on clinical activity may be collected during such trials than during Phase 1 clinical trials for non-oncology therapies. A single Phase 3 or Phase 2 trial may be sufficient in rare instances, including (i) where the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (ii) when in conjunction with other confirmatory evidence. Approval on the basis of a single trial may be subject to the requirement of additional post-approval studies.

Phase 1, Phase 2, Phase 3, and other types of clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including non-compliance with regulatory requirements or a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Concurrent with clinical trials, companies usually must complete some long-term preclinical testing, such as animal tests of reproductive toxicity and carcinogenicity, and must also develop additional information about the chemistry and physical characteristics of the drug or biologic and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

In addition, the manufacturer of an investigational biologic in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug or biologic.

U.S. review and approval processes

FDA approval of a BLA must be obtained before commercial marketing of the biologic product. The results of the preclinical tests and clinical trials, together with detailed information relating to the product's pharmacology, chemistry, manufacturing controls, or CMC, and proposed labeling, among other things, are submitted to the FDA as part of the BLA requesting approval to market the product for one or more indications.

The cost of preparing and submitting a BLA is substantial. Under the Prescription Drug User Fee Act, or PDUFA, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are

assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved BLA is also subject to an annual program fee.

The FDA reviews a BLA within 60 days of receipt to determine whether the application will be filed based on the FDA's determination that it is sufficiently complete to permit substantive review. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In that event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA files it. Once the submission is filed by the FDA, the FDA begins an in-depth, substantive review of the BLA.

The FDA reviews the BLA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, has an acceptable purity profile and whether the product candidate is being manufactured in accordance with cGMPs to assure and preserve the product candidate's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biologic products or biologic products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions on approval. During the product approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the product candidate. REMS involve additional risk minimization strategies to ensure that the benefits of the product outweigh the potential risks. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

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

On the basis of the BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the biologic 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 will not be approved in its present form. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. The FDA has committed to reviewing such resubmissions in two or six months, depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

The FDA has agreed to specified performance goals in the review of BLAs under the PDUFA. One such goal is to review standard BLAs within 10 months after the FDA files the BLA, and priority BLAs within six months, whereupon a review decision is to be made. The review process and the PDUFA goal date for both standard and priority review BLAs may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

If a product candidate receives regulatory approval, the FDA may require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biologic product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Compliance with cGMP requirements

Manufacturers of biologics must comply with applicable cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Manufacturers and others involved in the manufacture and distribution of such products also must register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Establishments may be subject to periodic, unannounced inspections by government authorities to ensure compliance with cGMP requirements and other laws. Discovery of problems may result in a government entity placing restrictions on a product, manufacturer or holder of an approved BLA, and may extend to requested product recalls or requiring withdrawal of the product from the market. The FDA will not approve a BLA 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 specification.

Expedited development and review programs

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition.

Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and

the specific indication for which it is being studied. The sponsor of a new biologic candidate can request the FDA to designate the candidate for a specific indication for fast track status concurrent with, or after, the submission of the IND for the candidate. The FDA must determine if the biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's BLA before the application is complete. This "rolling review" is available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval.

Breakthrough therapy designation may be granted for products that are intended, alone or in combination with one or more other products, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new biologic candidate may request that the FDA designate the candidate for a specific indication as a breakthrough therapy concurrent with, or after, the submission of the IND for the biologic candidate. The FDA must determine if the biological product qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team and taking other steps to design the clinical trials in an efficient manner.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

Accelerated approval may be granted for products that are intended to treat a serious or life-threatening condition and that generally provide a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. In clinical trials, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large studies to demonstrate a clinical or survival benefit. The accelerated approval pathway is contingent on the verification and description of the product's clinical benefit, which is generally in the form of at least one post-approval confirmatory trial. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated and/or fully enrolled prior to submission of the application or approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

The Food and Drug Omnibus Reform Act, or FDORA, included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study, which may include milestones such as a target date of study completion and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA not later than 180 days following approval and not less frequently than every 180 days thereafter until completion or termination of the study. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval, but may expedite the development or approval process.

Post-approval requirements

Rigorous and extensive FDA regulation of biologic products continues after approval, particularly with respect to cGMP requirements. Manufacturers are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation, and are subject to periodic inspections by the FDA. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval. Other post-approval requirements applicable to biologic products include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information and complying with electronic record and signature requirements. A sponsor also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities and promotional activities involving the internet.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. These actions could include refusal to approve pending applications or supplemental applications, withdrawal of an approval, clinical hold, suspension or termination of clinical trials by an IRB, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines or other monetary penalties, refusals of government contracts, mandated corrective advertising or communications with healthcare providers, debarment, restitution, disgorgement of profits or other civil or criminal penalties.

Orphan drug designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for treatment of rare diseases or conditions. In the United States, pursuant to the Orphan Drug Act, the FDA may grant orphan designation to a biological product intended to treat a rare disease or condition, which is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the biologic for the disease or condition will be recovered from sales of the product in the United States.

An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. The Office of Orphan Products Development at the FDA grants orphan drug designations based on acceptable confidential requests made under the regulatory provisions. The product must then go through the review and approval process like any other product. Orphan drug designation entitles a company to financial incentives, such as tax credits and user fee waivers, but does not convey any advantage in or shorten the duration of the regulatory review and approval process.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same drug, which includes biologics, as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same drug for the same indication for seven years, except in certain limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of product supply issues. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to orphan drug exclusivity. Competitors may receive approval of either a different drug for the same indication or the same drug for a different indication.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated and approved. The FDA may approve a second application for the same drug for a different use or a second application for a clinically superior version of the drug for the same use. Because healthcare professionals are free to prescribe products for off-label uses, the competitor's product could be used for the orphan indication despite another product's orphan exclusivity. The FDA cannot, however, approve the same drug made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

The FDA's determination of whether two ADCs are the same drug for purposes of orphan drug exclusivity is based on a determination of sameness of the monoclonal antibody element and the functional element of the conjugated molecule. Two ADCs are deemed to be the same product if the complementarity determining region sequences of the antibody and the functional element of the conjugated molecule are the same. A difference in either of those two elements can result in a determination that the molecules are different.

FDA approval and regulation of companion diagnostics

If use of an *in vitro* diagnostic is essential to the safe and effective use of a drug or biologic product, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, before or at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a biologic product or indication, the FDA generally will not approve the biologic product or new biologic product indication if the companion diagnostic device is not approved or cleared for that indication.

The FDA has also introduced the concept of a complementary diagnostic, which the FDA defines as a test that is not required but which provides significant information about the use of a drug. A complementary test can help guide treatment strategy and identify which patients are likely to derive the greatest benefit from therapy, and if approved by the FDA information regarding the *in vitro* diagnostic will be included in the therapeutic product labeling.

Approval or clearance of the companion or complementary diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. The review of *in vitro* companion or complementary diagnostics in conjunction with the review of our products will, therefore, likely involve coordination of review by the FDA's Center for Drug Evaluation and Research and Office of In Vitro Diagnostics. We may partner with a diagnostic provider to develop a companion or complementary diagnostic for certain of our product candidates. Review and approval of a companion or complementary diagnostic is typically done in parallel with development of the therapeutic product. However, it is possible that the FDA may permit approval of the companion or complementary diagnostic as a post-marketing commitment following a potential regulatory approval.

Under the FDCA, *in vitro* diagnostics, including companion and complementary diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA. The FDA has generally required *in vitro* companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a PMA for that diagnostic simultaneously with approval of the therapeutic.

The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic has adequate sensitivity and specificity, has adequate specimen and reagent stability, and produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, additional testing and/or restrictions on labeling, promotion, sale and distribution. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards are not maintained or problems are identified following initial marketing.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also register their establishments and list their devices with the FDA. A medical device manufacturer's manufacturing processes, and the processes of the device specification developer and repackager/relabeler (if different from the manufacturer) and initial importer (if manufactured outside of the United States) are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, importation, labeling, packaging and shipping of medical devices. Facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA.

Pediatric information

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biologic product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product candidate is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, the PREA generally does not apply to any biologic product candidate for an indication for which orphan designation has been granted with the exception of orphan-designated biologics if the product contains a new active ingredient and is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that FDA has determined is substantially relevant to the growth or progression of a pediatric cancer.

The Best Pharmaceuticals for Children Act, or BPCA, provides a six-month extension of any patent and non-patent exclusivity for a biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new biologic in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Additional controls for biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend biologics licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases within the United States.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of the product to the FDA together with a release protocol showing a summary of the lot manufacturing history and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before allowing the manufacturer to release the lots for distribution. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of a BLA, biologics manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Biosimilars and exclusivity

The Patient Protection and Affordable Care Act, or the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has licensed numerous biosimilars under the BPCIA, and has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the proposed biosimilar biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, an assessment of toxicity, and a clinical trial or studies though the FDA has broad discretion to set or waive certain biosimilar licensure data requirements. 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 in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose some hurdles to biosimilar product implementation which is still being evaluated by the FDA.

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 the applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created an exclusivity period for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The first biologic product submitted under the biosimilar abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against approval of an interchangeable biologic for the same condition of use for the earlier of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) eighteen months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

Patent term restoration and extension

In the United States, a patent claiming a new biologic product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. Assuming grant of the patent for which the extension is sought, the restoration period for a patent covering a product is typically one-half the time between the effective date of the IND involving human beings and the submission date of the BLA, plus the time between the submission date of the BLA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. 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 for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension in consultation with the FDA.

Regulation and procedures governing approval of medicinal products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials,

marketing authorization, commercial sales, post-market surveillance and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. Except in limited cases of compassionate use, it also requires the submission to the relevant competent authorities of a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

Clinical trial approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials (excluding non-interventional trials) conducted in the European Union has been implemented through national legislation of the member states. Under this system, the sponsor of a clinical trial must submit a request for authorization to the competent national authority of the European Union member state in which the clinical trial is to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant must obtain a favorable opinion from the competent ethics committee before starting a clinical trial. The clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, but it has not yet become effective. Its application is subject to the full functionality of the European Union clinical trials portal and database. According to the most recent official communications, the audit aiming to confirm the full functionality of the portal and database will be conducted in December 2020. The new Clinical Trials Regulation will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new legislation, which will be directly applicable in all member states, aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single-entry point and shorter deadlines for the assessment of clinical trial applications. The scientific assessment of a clinical trial to be conducted in more than one member state would be carried out once for all the concerned member states while other aspects (e.g., informed consent requirements) are assessed by each member state for its territory. In addition, sponsors must post clinical trial information (e.g., a summary of trial results) at the EudraCT website.

PRIME designation in the European Union

In March 2016, the European Medicines Agency (the "EMA") launched an initiative to facilitate development of product candidates of major interest from the point of view of public health and in particular from the point of view of therapeutic innovation. The PRIority MEdicines, or PRIME, scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Eligibility for the PRIME scheme depends on the availability of adequate preclinical and clinical data to justify a potential major public health interest prior to the initiation of confirmatory clinical trials at the proof-of-concept stage. Products from micro, small and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies and benefit from fee reductions with the EMA. Many benefits accrue to sponsors of product candidates with PRIME designation, including early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, scientific advice on key decision points for the preparation of the MAA and accelerated MAA assessment once a dossier has been submitted. More specifically, a kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Importantly, a dedicated EMA contact (rapporteur) from the Committee for Human Medicinal Products, or CHMP, or Committee for Advanced Therapies in the case of an advanced therapy, are appointed early in the PRIME scheme to provide continuous support and help to build knowledge ahead of a MAA.

Marketing authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union member states (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. In order to support the authorization of medicinal products for children, Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, an applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or a deferral for one or more of the measures included in the PIP. The requirement for a PIP also applies to applications for new indications, pharmaceutical forms or routes of administration for medicinal products that are already authorized.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure is optional. Manufacturers must demonstrate the quality, safety and efficacy of their products to the EMA, which provides an opinion regarding the MAA through the CHMP responsible for conducting an initial assessment of the product.

The maximum timeframe for the evaluation of an MAA by the CHMP is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment. The final decision on the MAA is issued by the European Commission, in light of the opinion delivered by the EMA, and after the member states have had an opportunity to comment on it.

With respect to medicinal products for which a centralized authorization is not mandatory, the applicant may choose between: (i) the national procedure provided for by a specific member state, for the marketing of the product in its territory, (ii) the decentralized procedure, for drug candidates that are not marketed in any of the member states but the applicant wishes to market them on more than one EU national territories or (iii) the mutual recognition procedure, which applies to products already authorized in a member state and whose marketing in other member states' territories is sought.

Regulatory data protection in the European Union

In the European Union, new chemical entities approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Regulation (EC) No 726/2004, as amended, and Directive 2001/83/EC, as amended.

These exclusivity periods apply only once from the first authorization granted to an applicant for a given active substance and they cannot be renewed when the same marketing authorization holder is granted new authorizations for new indications, strengths, pharmaceutical forms, administration routes or presentations of the same active substance. Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess another product (either generic, hybrid or biosimilar) application for a period of eight years. During the additional two-year period of market exclusivity, a generic, hybrid or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic, hybrid or biosimilar medicinal product can be marketed until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Patent term extensions in the European Union and other jurisdictions

The European Union also provides for patent term extension through Supplementary Protection Certificates, or SPCs. The rules and requirements for obtaining a SPC are similar to those in the United States. An SPC may extend the term of a patent for up to five years after its originally scheduled expiration date. In certain circumstances, these periods may be extended for six additional months if pediatric exclusivity is obtained. Although SPCs are available throughout the European Union, sponsors must apply on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the European Union.

Periods of authorization and renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state, depending on the procedure through which the marketing authorization has been granted. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the drug on the European Union market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization is granted ceases to be valid.

Regulatory requirements after marketing authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's good manufacturing practices ("GMP") requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in the manufacturing, processing and packing of drugs to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended.

Orphan drug designation and exclusivity

Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (i) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or (ii) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug for which the orphan designation is requested will be of significant benefit to those affected by that condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory and scientific assistance and the possibility to apply for a centralized European Union marketing authorization. In particular, an orphan drug designation leads to a 10-year period of market exclusivity from the granting of the concerned medicinal product marketing authorization for the particular indication. During this market exclusivity period, neither the EMA nor the member states can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar or identical active substance, or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable so as to not to justify market exclusivity.

General Data Protection Regulation (the "GDPR")

The collection, use, disclosure, transfer or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the Regulation (EU) No. 2016/679, the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global turnover of the preceding financial year, 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. Compliance with the GDPR will be a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

Coverage and reimbursement

Sales of our product candidates, if approved, will depend, in part, on the extent to which such products will be covered by third-party payors, such as government healthcare programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage or reducing reimbursements for medical products and services. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician usage of our product candidates, once approved, and have a material adverse effect on our sales, results of operations and financial condition.

Other U.S. healthcare laws and compliance requirements

In the United States, biotechnology company activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS (e.g., the Office of Inspector General and the Office for Civil Rights), the U.S. Department of Justice, or the DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. The laws biotechnology companies may have to comply with include the anti-fraud and abuse provisions of the Social Security Act, the federal false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, recommending or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and/or formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the

Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. In addition, the statutory exceptions and regulatory safe harbors are subject to change. Additionally, the intent standard under the Anti-Kickback Statute was amended by the ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

Federal false claims laws, including the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the civil False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Pharmaceutical and other biotechnology companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus generally non-reimbursable, uses and purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes.

HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain types of advance practice nurses and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of such providers, and to report annually certain ownership and investment interests held by physicians and their immediate family members.

Violation of any of the federal and state healthcare laws described above or any other governmental regulations may result in penalties, including without limitation, significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, refusal to enter into government contracts, oversight monitoring, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings.

Federal and state data privacy and security laws

Under HIPAA, HHS has issued regulations to protect the privacy and security of protected health information used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their regulations, including the final omnibus rule published on January 25, 2013, also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that are applicable to our business. In addition to possible federal administrative, civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. Accordingly, state attorneys general have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. New laws and regulations governing privacy and security may be adopted in the future as well.

Additionally, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not preempted by HIPAA, thus complicating compliance efforts. For example, the California Consumer Privacy Act, or CCPA, creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA went into effect on January 1, 2020 and requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. On November 3, 2020, California voters approved a new privacy law, the California Privacy Rights Act, or the CPRA, which significantly modifies the CCPA, including by expanding consumers' rights with respect to certain personal information and creating a new state agency to oversee implementation and enforcement efforts. The CCPA and CPRA provide for unlimited civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CPRA took effect in most material respects on January 1, 2023. CCPA enforcement thus far has been limited; it has not been subject to significant litigation and judicial interpretation. As a result, it remains unclear

how various provisions of the CCPA will be interpreted and enforced. State laws are changing rapidly and there is discussion in the U.S. of a new comprehensive federal data privacy law to which we would become subject if it is enacted. In addition, Virginia's Consumer Data Protection Act, which took effect on January 1, 2023, requires businesses subject to the legislation to conduct data protection assessments in certain circumstances and requires opt-in consent from consumers to acquire and process their sensitive personal information, which includes information revealing a consumer's physical and mental health diagnosis and genetic and biometric information that can identify a consumer. Colorado enacted the Colorado Privacy Act, and Connecticut enacted the Connecticut Data Privacy Act, each of which took effect on July 1, 2023, and Utah enacted the Consumer Privacy Act, which became effective on December 31, 2023, and each of these laws may increase the complexity, variation in requirements, restrictions, and potential legal risks, and could require increased compliance costs and changes in business practices and policies. Other states have also enacted, proposed, or are considering proposing, data privacy laws.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more of such privacy and data security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and reporting requirements in multiple jurisdictions could increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any of the privacy or data security laws or regulations described above that are applicable to us, or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a consent decree or similar agreement 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. To the extent that any product candidates we may develop, once approved, are sold in a foreign country, we may be subject to similar foreign laws.

Healthcare reform

Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. Several healthcare reform proposals culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which, among other things, allows HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. Only high-expenditure single-source biologics that have been approved for at least 11 years (7 years for drugs) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. Negotiations for Medicare Part D products take place in 2024 with the negotiated price taking effect in 2026, and negotiations for Medicare Part B products will begin in 2026 with the negotiated price taking effect in 2028. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations. HHS will announce the negotiated maximum fair prices by September 1, 2024, and this price cap, which cannot exceed a statutory ceiling price, will go into effect on January 1, 2026. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including significant civil monetary penalties. These provisions have been and may continue to be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the biopharmaceutical industry and the pricing of prescription drug products. Additional state and federal healthcare reform measures could be adopted in the future.

Human Capital Management

Employees. As of December 31, 2023, we employed 65 employees. We also engaged 21 independent contractors located in China as of December 31, 2023 pursuant to our relationship with BioDuro-Sundia, a U.S.-based provider of preclinical development services. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Compensation and Benefits Program. Our compensation program is designed to attract and reward talented individuals who possess the skills necessary to support our business objectives, assist in the achievement of our strategic goals and create long-term value for our stockholders. We provide employees with compensation packages that include base salary, annual incentive bonuses, and long-term equity awards tied to the value of our stock price. We believe that a compensation program with both short-term and long-term awards provides fair and competitive compensation and aligns employee and stockholder interests, including by incentivizing business and individual performance (pay for performance), motivating based on long-term company performance and integrating compensation with our business plans. In addition to cash and equity compensation, we also offer employees benefits such as life and health (medical, dental & vision) insurance, flexible spending accounts for health and dependent care needs, paid time off, paid parental leave, participation in our Employee Stock Purchase Plan and a 401(k) plan. In addition to our benefits, we offer wellness and stress management support which includes an on-site gym, company-wide wellness activities, wellness resources that are shared with employees each month, an Employee Assistance Program with counseling, and flexible work arrangements.

Diversity and Inclusion. We believe that an equitable and inclusive environment with diverse teams produces more creative solutions, results in better, more innovative products and services and is crucial to our efforts to attract and retain key talent. Our current efforts are focused on four primary areas:

- Safe work environment. We provide training to all employees to improve their understanding of behaviors that can be perceived as discriminatory, exclusionary, and/or harassing, and provide safe avenues for employees to report such behaviors.
- Equal employment opportunity. We ensure that our practices and processes attract a diverse range of candidate, and that candidates are recruited, hired, paid, assigned, developed, and promoted based on merit and their alignment to our values.
- Learning and development opportunities. To support our employees in reaching their full potential, we offer a wide range of internal and external learning and development opportunities.
- Community Involvement. We aim to give back to the communities where we live and work, and believe that this commitment helps in our efforts to attract and retain employees. We work with local universities to introduce and promote careers in science and biotechnology through internship opportunities.

Corporate Information

Our business and predecessor entity was founded in March 2007. In July 2020, we converted from a limited liability company into a Delaware corporation pursuant to a statutory conversion and changed our name to BioAtla, Inc. Our principal executive offices are located at 11085 Torreyana Road, San Diego, California 92121, and our telephone number is (858) 558-0708. Our corporate website address is www.bioatla.com. Information contained on, or that may be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered a part of this Annual Report on Form 10-K.

We have obtained a registered trademark for BioAtla® in the United States. This Annual Report on Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Available Information

We make available, free of charge through our website www.bioatla.com, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to those reports, filed or furnished pursuant to Sections 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after they have been electronically filed with, or furnished to, the SEC.

The SEC maintains an internet site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

ITEM 1A. Risk Factors

Risk Factor Summary

Investing in our common stock involves a high degree of risk. You should carefully consider all information in this Annual Report on Form 10-K before purchasing our common stock. These risks and uncertainties include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, and we have a history of significant losses and expect to continue to incur significant losses for the foreseeable future.
- We will require substantial additional capital to finance our operations, and if we fail to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs or future commercialization efforts.
- Our product candidates may fail in development or suffer delays that adversely affect their commercial viability.
- We are substantially dependent on the success of our patented CAB technology platform, and our future success depends heavily on the successful development of this platform.
- We may expend our resources to pursue particular product candidates and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.
- The market may not be receptive to our product candidates because they are based on our novel therapeutic modality, and we may not generate any future revenue from the sale or licensing of product candidates.
- Results from early-stage clinical trials may not be predictive of results from late-stage or other clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.

- Interim, topline and preliminary data 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 and verification procedures that could result in material changes in the final data.
- Delays in the commencement and completion of clinical trials could increase costs and delay or prevent regulatory approval and commercialization of our product candidates.
- We face competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms.
- We may be unable to obtain U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates.
- We intend to seek approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways, if available, and if we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals.
- Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.
- If we fail to attract and retain qualified senior management and key scientific personnel, our business may be materially and adversely affected.
- If we are unable to establish sales, marketing and distribution capabilities on our own or through third parties, we may not be able to market and sell our product candidates, if approved, effectively in the United States and foreign jurisdictions or generate product revenue.
- A portion of our research and development activities take place in China, and uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations, a trade war, deterioration of international relations, or political unrest in China could materially adversely affect our business, financial condition and results of operations.
- We face risks related to health epidemics and outbreaks which could significantly disrupt our preclinical studies and could affect enrollment of patients in our clinical trials. Continuation and increasing severity of these conditions could delay or prevent our receipt of necessary regulatory approvals.
- If we fail to enter into collaborations with third parties for the development and commercialization of certain of our product candidates, or if our current and future collaborations are not successful, we may not be able to capitalize on the market potential of our patented technology platform and resulting product candidates.
- If we are not able to obtain, maintain and protect our intellectual property rights in any product candidates or technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, third parties could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market.
- Intellectual property rights of third parties could prevent or delay our drug discovery and development efforts and could adversely affect our ability to commercialize our product candidates, and we might be required to litigate or obtain licenses from third parties in order to discover, develop or market our product candidates.
- The future issuance of equity or of debt securities that are convertible into equity will dilute our share capital.
- Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval and their interests may conflict with your interests as an owner of our common stock.

Risk Factors

Risks related to our financial position and need for additional capital

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have a history of significant losses and we expect to continue to incur significant losses for the foreseeable future, which together with our limited operating history, makes it difficult to assess our future viability.

We are a Phase 2 clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We have no products approved for commercial sale and have not generated any revenue from product sales. Since the commencement of our operations, we have focused substantially all of our resources on conducting research and development activities, including drug discovery, preclinical studies and clinical trials of our product candidates, including the ongoing Phase 2 clinical trials of mecbotamab vedotin (BA3011), ozuriftamab vedotin (BA3021), evalstotug (BA3071), and the ongoing Phase 1 clinical trial of BA3182 (CAB-EpCAM x CAB-CD3), establishing and maintaining our intellectual property portfolio, manufacturing clinical and research material through third parties, hiring personnel, establishing product development and commercialization collaborations with third parties, raising capital, and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to assess our future viability than it could be if we had a longer operating history.

We have incurred significant losses to date. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current and future product candidates. Our net losses were $123.5 million and $106.5 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $416.3 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We do not expect to generate meaningful revenue from product sales for the foreseeable future, and we expect to continue to incur significant operating expenses for the foreseeable future due to the cost of research and development, including identifying and designing product candidates and conducting preclinical studies and clinical trials, and the regulatory approval process for our product candidates. In the near term, we expect that these expenses begin to decrease as we complete enrollment for certain clinical trials, however, these expenses, and the potential for losses, may generally increase as we progress our lead product candidates through the regulatory approval process. We also expect that our expenses will vary as a result of macroeconomic factors, including inflation. For example, recently, several of our vendors have passed along price increases they have experienced in their own business as a result of inflation.

However, the amount of our future expenses and potential losses is uncertain. Our ability to achieve profitability, if ever, will depend on, among other things, our successfully developing product candidates, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms and potentially establishing a sales and marketing organization or suitable third-party alternatives to commercialize any approved product. If we, or our existing or future collaborators, are unable to develop and commercialize one or more of our product candidates or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve profitability, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs or future commercialization efforts.

The development of biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we will continue to incur significant expense in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, mecbotamab vedotin, ozuriftamab vedotin, evalstotug, and BA3182. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other comparable foreign regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of December 31, 2023, we had approximately $111.5 million in cash and cash equivalents. Based on our current operating plan, our current cash and cash equivalents are expected to be sufficient to fund our ongoing operations for a period of at least twelve months from the date the financial statements included in this report are issued. Our current operating plan includes prioritization of our programs and focusing on clinical development of selected assets and indications. Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We plan to use our existing cash and cash equivalents to fund the research and development of our product candidates and development programs, and to fund working capital and other general corporate purposes.

Advancing the development of our product candidates will require a significant amount of capital. Our existing cash and cash equivalents may not be sufficient to fund any of our product candidates through regulatory approval. Because the length of time and activities associated with successful research and development of any individual product candidate are highly uncertain, we are unable to estimate the actual funds we will require for development, marketing approval and commercialization activities. The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of our ongoing clinical trials for mecbotamab vedotin, ozuriftamab vedotin, evalstotug, and BA3182;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of our collaborators with whom we have entered, or may in the future enter, into collaboration agreements and research and development agreements;
- the timing and amount of milestone payments we may receive under our collaboration agreements;
- our ability to maintain our current licenses, collaboration and research and development programs or possibly establish new collaboration arrangements;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the cost and timing of regulatory approvals; and

- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates and satisfy our obligations as a public company.

If we are unable to obtain funding on a timely basis, including under our current or future collaborations, or on acceptable terms, we may have to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We cannot assure you that such financing will be available at acceptable terms to us, if at all. Failure to generate sufficient cash flows from operations, raise additional capital, and reduce discretionary spending should additional capital not become available could have a material adverse effect on our ability to achieve our intended business objectives. To the extent that we raise additional capital through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates. We may also have to forego future revenue streams of research programs at an earlier stage of development or on less favorable terms than we would otherwise choose or have to grant licenses on terms that may not be favorable to us. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Our financial condition could be adversely affected by general conditions in the global economy and in the global financial markets. For example, global financial crises have caused extreme volatility and disruptions in the capital and credit markets. Additionally, although we had no direct exposure to the March 2023 failure of Silicon Valley Bank, its potential near- and long-term effects on the biotechnology industry and its participants such as our vendors, suppliers, collaborators and investors, may also adversely affect our financial condition, operations and stock price. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. A severe or prolonged economic downturn, such as a global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financings, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, licensing product rights, entering into product development collaborations, acquiring other businesses, products or technology or declaring dividends. If we are unable to obtain additional funding from these or other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delay, scale back or stop certain research and development programs.

We invest a portion of our cash in a money market fund, which is vulnerable to market-specific risks that could adversely affect our business and financial condition.

We invest a portion of our cash in a money market fund backed by U.S. government securities. All securities are subject to risk, including fluctuations in interest rates, credit risk, market risk and systemic economic risk. Changes or movements in any of these investment-related risk items may result in a loss or impairment to our invested cash and may have a material adverse effect on our business and financial condition.

Risks related to the discovery, development and commercialization of our product candidates

Our current product candidates are in various stages of development. Our product candidates may fail in development or suffer delays that adversely affect their commercial viability. If we or our existing or future collaborators are unable to complete development of, obtain regulatory approval for or commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We have no products on the market and our product candidates are in various stages of development. We are currently conducting Phase 2 clinical trials of mecbotamab vedotin, ozuriftamab vedotin, and evalstotug; we have begun dosing patients in our Phase 1 trial of BA3182 and various other product candidates are in earlier stages of development. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and, if approved, successfully commercializing our product candidates, either alone or with third parties. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety, efficacy, purity and potency of our product candidates. Any product candidate can unexpectedly fail at any stage of preclinical or clinical development and the historical failure rate for product candidates is high. The results from preclinical testing of a product candidate may not predict the results that will be obtained in later clinical trials of the product candidate. We or our existing or future collaborators may experience issues that delay or prevent clinical testing and regulatory approval of, or our ability to commercialize, product candidates, including, among others:

- delays in our clinical trials resulting from external factors including global conflicts and health epidemics;
- negative or inconclusive results from preclinical testing or clinical trials leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by participants in clinical trials or by individuals using therapeutic biologics that share characteristics with our product candidates;
- delays in submitting INDs or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators or institutional review boards, or IRBs, to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;

- conditions imposed by the FDA or comparable foreign authorities, including the EMA, regarding the scope or design of clinical trials;
- delays in enrolling patients in clinical trials;
- high drop-out rates of patients;
- inadequate drug materials or other supplies necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness of our product candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- deficiencies in our third-party manufacturers' manufacturing processes or facilities;
- success or further approval of competitor products approved in indications in which we undertake development of our product candidates, which may change the standard of care or change the standard for approval of our product candidates in our proposed indications;
- failure of any third-party contractors, investigators or contract research organizations, or CROs, to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology or product candidates in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies, including the EMA.

Because CABs represent a new generation of antibodies, a delay or failure in development of any CAB product candidate could represent a major set-back for our patented technology platform and for our company generally.

Results from early-stage clinical trials may not be predictive of results from late-stage or other clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.

Positive and promising results from preclinical studies and early-stage clinical trials may not be predictive of results from late-stage clinical trials or from clinical trials of the same product candidates for the treatment of other indications. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Late-stage clinical trials could differ in significant ways from early-stage clinical trials, including changes to inclusion and exclusion criteria, efficacy endpoints, dosing regimen and statistical design.

Moreover, success in clinical trials in a particular indication does not guarantee that a product candidate will be successful for the treatment of other indications. Many companies in the biopharmaceutical industry have suffered significant setbacks in late-stage clinical trials after achieving encouraging or positive results in early-stage development. We cannot assure you that we will not face similar setbacks in our ongoing or planned clinical trials or in any subsequent or post-marketing confirmatory clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval. We cannot guarantee that the FDA will agree with our clinical trial plans, and we cannot assure you that the FDA will agree that the results from our trials will be sufficient to support approval of any of our product candidates. For example, the objective response rates on our primary endpoints may not be sufficient, we may not demonstrate a sufficient duration of response, or there may be limitations with the total sample size of our studies and dose selection strategy. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential. Furthermore, the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA, EMA or comparable foreign regulatory authorities delaying, limiting or denying approval of our product candidates.

Furthermore, in 2023, enrollment was completed in multi-center investigator-initiated clinical trials in Canada of mecbotamab vedotin and ozuriftamab vedotin in patients with platinum-resistant ovarian cancer using the lower effective dose of 1.8mg/kg Q2W of the two doses available. We do not control the design or administration of these or any other investigator-initiated trials that may be conducted, nor the submission or approval of any IND or foreign equivalent required to conduct any such trials. Any investigator-initiated trials could, depending on the actions of such third parties, jeopardize the validity of the clinical data generated, identify significant concerns with respect to our product candidates that could impact our findings or clinical trials, and adversely affect our ability to obtain marketing approval from the FDA or other applicable regulatory authorities. To the extent the results of these or other investigator-initiated trials are inconsistent with, or different from, the results of our ongoing or planned company-sponsored trials or raise concerns regarding our product candidates, the FDA or a foreign regulatory authority may question the results of the company-sponsored trial, or subject such results to greater scrutiny than it otherwise would. In these circumstances, the FDA or such foreign regulatory authorities may require us to obtain and submit additional clinical data, which could delay clinical development or marketing approval of our product candidates. In addition, while investigator-initiated trials could be useful to inform our

own clinical development efforts, there is no guarantee that we will be able to use the data from these trials to form the basis for regulatory approval of our product candidates.

We are substantially dependent on the success of our patented CAB technology platform, and our future success depends heavily on the successful development of this platform.

We use our CAB technology platform to develop product candidates for cancer therapies. Any failures or setbacks involving our CAB technology platform, including adverse events, could have a detrimental impact on all of our product candidates and our research pipeline. For example, we may uncover a previously unknown risk associated with CABs or other issues that may be more problematic than we currently believe, which may prolong the period of observation required for obtaining, necessitate additional clinical testing or result in the failure to obtain, regulatory approval. If our CAB technology is not safe in certain product candidates, we could be required to abandon or redesign all of our current product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be successful in our efforts to use and expand our patented CAB technology platform to continue to build a pipeline of product candidates and develop marketable products.

We are using our patented technology platform to develop CABs in oncology indications with our lead product candidates mecbotamab vedotin, ozuriftamab vedotin, evalstotug, and BA3182, as well as continuing to build our pipeline of product candidates. Our business depends not only on our ability to successfully develop, obtain regulatory approval for, and commercialize the product candidates we currently have in clinical and preclinical development, but to continue to generate new product candidates through our platform. Even if we are successful in continuing to build our pipeline and further progress the clinical development of our current product candidates, any additional product candidates may not be suitable for clinical development, including as a result of harmful side effects, manufacturing issues, limited efficacy or other characteristics that indicate that they are unlikely to be products that will succeed in clinical development, receive marketing approval or achieve market acceptance. If we cannot validate our technology platform by successfully commercializing CAB product candidates, we may not be able to obtain product, licensing or collaboration revenue in future periods, which would adversely affect our business, financial condition, results of operations and prospects.

We may expend our resources to pursue particular product candidates and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

As a result of our limited financial and managerial resources, we must make strategic decisions as to which targets and product candidates to pursue and may forego or delay pursuit of opportunities with other targets or product candidates or for other indications that later prove to have greater commercial potential. For example, we are exploring potential strategic collaboration with third parties to accelerate development of certain assets. In addition, we have no plans to internally explore additional dosing regimens for certain indications, and do not intend to pursue ovarian cancer, and are focusing development on selected assets and indications. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Failure to properly assess potential product candidates could result in our focus on product candidates with low market potential, which would harm our business, financial condition, results of operations and prospects. Our spending on current and future research and development programs and product candidates for specific targets or indications may not yield any commercially viable products. Our understanding and evaluation of biological targets for the discovery and development of new CAB product candidates may fail to identify challenges encountered in subsequent preclinical and clinical development. If we do not accurately evaluate the likelihood of clinical trial success, commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

If the market opportunities for any product that we develop are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

We focus our product candidate development on therapeutic CAB antibodies for the treatment of various oncology indications, such as soft tissue and bone sarcoma, NSCLC, melanoma, and head and neck cancer among others. Our projections of addressable patient populations that may benefit from treatment with our product candidates are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, physician interviews, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

The market may not be receptive to our product candidates because they are based on our novel therapeutic modality, and we may not generate any future revenue from the sale or licensing of product candidates.

The product candidates that we are developing are primarily based on our patented CAB technology platform, which uses new technologies to create our novel therapeutic approach. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt a product or treatment based on our patented technology platform, and we may not be able to convince patients, the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. Market acceptance of our product candidates will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the safety and efficacy of our product candidates;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory authority, including the EMA;
- the willingness of patients to obtain new biopsies or consent to provide existing tumor tissue specimens to support our clinical trials;
- relative convenience and ease of administration of our product candidates;
- the willingness of patients to accept any new methods of administration;
- the success of any physician education programs;
- the availability of adequate government and third-party payor reimbursement;
- the pricing of our products, particularly as compared to alternative treatments; and
- availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

If any product candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preliminary, preplanned interim and topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and/or are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, preplanned interim or topline data from our clinical trials. These data and related findings and conclusions may only reflect certain endpoints rather than all endpoints and are subject to change. For example, we may report tumor responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report preplanned interim analyses of the clinical trials we may complete, which 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. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary preplanned interim or topline data that we report differ from later, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Delays in the commencement and completion of clinical trials could increase costs and delay or prevent regulatory approval and commercialization of our product candidates.

We cannot guarantee that clinical trials of our product candidates will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of the clinical trial process, and other events may cause us to temporarily or permanently stop a clinical trial. Events that may prevent successful or timely commencement and completion of clinical development include:

- negative preclinical data;
- delays in receiving the required regulatory clearance from the appropriate regulatory authorities to commence clinical trials or amend clinical trial protocols, including any objections to our INDs or protocol amendments from the FDA;
- delays in reaching, or a failure to reach, a consensus with regulatory authorities on study design;
- delays in reaching, or failure to reach, agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- difficulties in obtaining IRB approval at each site;
- challenges in recruiting suitable patients to participate in a trial;

- the inability to enroll a sufficient number of patients in clinical trials to ensure adequate statistical power to detect statistically significant treatment effects;
- difficulties in having patients complete a trial or return for post-treatment follow-up;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a clinical trial;
- unforeseen safety issues, including occurrence of treatment emergent adverse events, or TEAEs, associated with the product candidate that are viewed to outweigh the product candidate's potential benefits;
- difficulties in adding new clinical trial sites;
- ambiguous or negative interim results;
- lack of adequate funding to continue the clinical trial;
- difficulties in manufacturing sufficient quantities of product candidate acceptable for use in clinical trials in a timely manner, or at all; or
- health epidemics and outbreaks, including the COVID-19 pandemic, which in the past has resulted in, and in the future may result in, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, 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 our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. 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.

In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Our clinical trial results may not be successful, or even if successful, may not lead to regulatory approval.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays or difficulties in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials on our current timelines, or at all, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Enrollment in our clinical trials may be slower than we anticipate, leading to delays in our development timelines.

Patient enrollment and retention in clinical trials depends on many factors, including the size and nature of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, delays in enrollment due to travel or quarantine policies, or other factors related to health epidemics or pandemics, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, including criteria related to biomarkers, our ability to obtain and maintain patient consents, including any additional consents necessary for enrollment of adolescent patients, and our ability to successfully complete prerequisite studies before enrolling certain patient populations. Furthermore, any negative results or new safety signals we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting. Similarly, results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one or more of our trials.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. In addition, we rely on clinical trial sites to ensure timely conduct of our clinical trials and, while we have entered into agreements governing their services, we are limited in our ability to compel their actual performance.

Our product candidates may cause undesirable and unforeseen side effects or have other properties impacting safety that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial. Many compounds developed in the biopharmaceutical industry that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented their further development. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

In our clinical trials for our antibody-drug conjugates mecbotamab vedotin and ozuriftamab vedotin, we have observed adverse events such as reversible myelosuppression, transient liver enzyme elevations, pyrexia, or fever, metabolic disturbances and peripheral neuropathy. In our clinical trial for evalstotug, we have observed infusion-related reactions and immune-related adverse events. We may also observe undesirable side effects in clinical trials for our other product candidates.

For our current and future clinical trials, we have contracted with and expect to continue to contract with CROs experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, they may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials and which could jeopardize regulatory approval.

Further, clinical trials by their nature test product candidates in only samples of the potential patient populations. With a limited number of patients and limited duration of exposure in such trials, rare and severe side effects of our product candidates may not be uncovered until a significantly larger number of patients are exposed to the product candidate. For example, while we believe that mecbotamab vedotin, ozuriftamab vedotin, and evalstotug have demonstrated manageable tolerability profiles thus far, we cannot assure you that these and our other product candidates will not cause more severe side effects in a greater proportion of patients.

In addition, mecbotamab vedotin, ozuriftamab vedotin, and evalstotug are being studied in combination with other therapies, which may exacerbate adverse events associated with the therapy. Patients treated with mecbotamab vedotin, ozuriftamab vedotin or our other product candidates may also be undergoing surgical, radiation or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials.

The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, some of the late-stage patients enrolled in our mecbotamab vedotin and ozuriftamab vedotin clinical trials may die or experience major clinical events either during the course of our clinical trials or after participating in such trials due mainly to the gravity of their illness, which has occurred in the past.

In the event that any of our product candidates receive regulatory approval, and we or others later identify undesirable and unforeseen side effects caused by such product, negative consequences, including any of the following, could occur:

- regulatory authorities may suspend, limit or withdraw their approval of such product, or seek an injunction against its manufacture or distribution;
- we may be required to conduct additional clinical trials or post-approval studies;
- we may be requested or 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 boxed warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a REMS and/or create a Medication Guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- the product may become less competitive; and
- our reputation may suffer.

Any of these 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 to us, which would materially and adversely affect our results of operations and business. In addition, if one or more of our product candidates prove to be unsafe, our business, financial condition, results of operations and prospects may be materially and adversely affected.

We are developing certain of our product candidates in combination with other therapies, and regulatory approval, safety or supply issues with these other therapies may delay or prevent the development and approval of our product candidates.

Currently, we are evaluating the use of each of mecbotamab vedotin, ozuriftamab vedotin, and evalstotug in combination with an anti-PD-1 inhibitor. In the future, we may explore the use of these or our other product candidates in combination with other therapies. If we choose to develop a product candidate for use in combination with an approved therapy, we are subject to the risk that the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions could revoke approval of, or that safety, efficacy, manufacturing or supply issues could arise with, the therapy used in combination with our product candidate. If the therapies we use in combination with our product candidates are replaced as the standard of care, the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our product candidates, if approved, being removed from the market or being less successful commercially.

Where we develop a product candidate for use in combination with a therapy that has not been approved by the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions, we will not be able to market our product candidate for use in combination with such an unapproved therapy, unless and until the unapproved therapy receives regulatory approval. In addition, other companies may also develop their products or product candidates in combination with the unapproved therapies with which we are developing our product candidates for use in combination. Any setbacks in these companies' clinical trials, including the emergence of serious adverse effects, may delay or prevent the development and approval of our product candidates.

If the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions do not approve or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, therapies we choose to evaluate in combination with any of our product candidates, we may be unable to obtain regulatory approval of or to commercialize such product candidates in combination with these therapies.

If safe and effective use of any of our product candidates, such as mecbotamab vedotin and ozuriftamab vedotin, depends on a companion diagnostic test, then the FDA generally will require approval or clearance of that companion diagnostic before or at the same time that the FDA approves our product candidates, if at all. If we are unable to successfully develop companion diagnostic tests for our product candidates, experience significant delays in doing so, rely on third parties in the development of such companion diagnostic tests, or do not obtain or face delays in obtaining FDA approval of a companion diagnostic test, the full commercial potential of our product candidates and our ability to generate revenue will be materially impaired.

If use of a companion diagnostic test is determined to be essential for the safe and effective use of any of our product candidates, such as mecbotamab vedotin and ozuriftamab vedotin, then the FDA generally will require approval or clearance of that companion diagnostic before or at the same time that the FDA approves our product candidates, if at all. The FDA has generally required *in vitro* companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a PMA for that diagnostic simultaneously with approval of the therapeutic. The process of obtaining or creating such diagnostic and obtaining PMA approval is time-consuming and costly and a delay in diagnostic approval could delay drug approval. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to regulatory approval requirements. For example, we have in the past explored predictive biomarkers, such as the TmPS, which measures AXL and ROR2 expression levels on the tumor membrane, to help inform which patients may be most suitable for treatment with mecbotamab vedotin and ozuriftamab vedotin. Currently, patients with negative or only 1% TmPS scores have experienced clinical benefit in our ongoing clinical trials. However, if the AXL and/or ROR2 TmPS scores predict those most likely to experience clinical benefit, we may be required to pursue the further use of a companion diagnostic in our mecbotamab vedotin or ozuriftamab vedotin clinical trials, and the available market for mecbotamab vedotin or ozuriftamab vedotin, both in patient numbers and patient acceptance of the protocol, could be limited. In addition, we expect to rely on third parties for the design, development and manufacture of companion diagnostic tests for any of our product candidates that require such tests.

On April 13, 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. We will continue to evaluate the impact of this guidance on our companion diagnostic development and strategy. This guidance and future policies from the FDA and other regulatory authorities may impact our development of a companion diagnostic for our product candidates and result in delays in regulatory approval. We may be required to conduct additional studies to support a broader claim. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon our companion diagnostic development plans or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our approved products and adversely affect our business, financial condition, results of operations and prospects.

If the FDA, EMA or a comparable foreign regulatory authority requires approval of a companion diagnostic for any of our product candidates, whether before or after it obtains marketing approval, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for such product candidate. If we or our third-party collaborators experience any delay in developing or obtaining regulatory approval of a companion diagnostic, we may be unable to enroll enough patients for our current and planned clinical trials, the development of our product candidates may be adversely affected or we may not obtain marketing approval, and we may not realize the full commercial potential of our product candidates, including mecbotamab vedotin and ozuriftamab vedotin.

We face competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.

The development and commercialization of drugs and therapeutic biologics is highly competitive. We compete with a variety of multinational biopharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. Our competitors have developed, are developing and will develop product candidates and processes competitive with our product candidates. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are developing product candidates. We believe that while our patented CAB technology platform, its associated intellectual property and our scientific and technical know-how give us a competitive advantage in this space, competition from many sources remains. Our success will partially depend on our ability to develop and protect therapeutics that are safer and more effective than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective or less expensive than the therapeutics we develop.

Although we do not believe competing companies have selective CAB technology, there is a wide array of activity in multiple areas of immune-based cellular therapies for oncology including CAR-T and T-cell receptor therapies. Certain companies are also pursuing antibody therapies in immuno-oncology, ADCs and various prodrug biologic products designed to be preferentially activated at tumor sites. There are several FDA approved ADC products and several companies in various stages of clinical development of ADCs mostly directed at oncology indications, a key feature of our product candidates mecbotamab vedotin and ozuriftamab vedotin. There are also companies developing technologies designed to deliver biologics and chemotherapeutic agents with some targeting capabilities. In addition, if any of our product candidates are approved in oncology indications, they may compete with existing biologics and small molecule therapies or may be used in combination with existing therapies. There are also many other therapies under development that are intended to treat the same cancers that we are targeting or may target with our CAB platform, including through approaches that could prove to be more effective, have fewer side effects, be cheaper to manufacture, be more convenient to administer or have other advantages over any products resulting from our technologies.

Many of our competitors, either alone or with strategic partners, have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive. Accelerated merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. In addition, our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development of our programs.

Our commercial opportunity could be substantially limited in the event that our competitors develop and commercialize products that are more effective, safer, less toxic or more convenient than products we may develop. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of our products' entry. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Our biologic product candidates for which we intend to seek approval may face competition through an abbreviated pathway.

The ACA includes a subtitle called the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. 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 the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for our product candidates.

There is a risk that any product candidates we may develop that are approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not

consider any product candidates we may develop to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated.

Our business entails a significant risk of product liability, and if we are unable to obtain sufficient insurance coverage, such failure could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We expect to be exposed to significant product liability risks inherent in the development, testing and manufacturing of our product candidates and products, if approved. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our third-party manufacturer's manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, including limitations on the approved indications for which our product candidates may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. In addition, we may be subject to liability based on the actions of our existing or future collaborators in connection with their development of products using our CAB technology. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks related to regulatory approval and other legal compliance matters

We may be unable to obtain U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates.

Our product candidates are subject to extensive governmental regulations relating to, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be successfully completed in the United States and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, lengthy, time-consuming, uncertain and subject to unanticipated delays. We have not previously submitted a BLA to the FDA, or similar drug approval filings to comparable foreign regulatory authorities, for any product candidate, and it is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us or our existing or future collaborators to begin selling them.

We have not completed any large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate, and numerous other factors including the substantial discretion of regulatory authorities. The standards that the FDA and its foreign counterparts, including the EMA, use when regulating us and our existing or future collaborators require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. For example, the Oncology Center of Excellence within the FDA has advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, may require sponsors to spend additional time and resources to further explore a product candidate's dose-response relationship to facilitate optimum dose selection in a target population. Other Oncology Center of Excellence initiatives have included Project FrontRunner, an initiative with a goal of developing a framework for identifying candidate drugs for initial clinical development in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options, and Project Equity, which is an initiative to ensure that the data submitted to the FDA for approval of oncology medical products adequately reflects the demographic representation of patients for whom the medical products are intended. We are considering these and other policy changes as they relate to our programs.

In addition, our product candidates could fail to receive regulatory approval for many reasons including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe, pure and potent for its proposed indication;
- the results of clinical trials may fail to achieve 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;
- we may be unable to demonstrate that the dose for the product candidate has been optimized;

- we may be unable to demonstrate a sufficient response rate or duration of response for a product candidate;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data submitted in support of regulatory approval;
- the data collected from preclinical studies and clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other regulatory submission necessary to obtain regulatory approval in the United States or elsewhere; and
- we or our contractors may not meet the current Good Manufacturing Practices, or cGMPs, and other applicable requirements for manufacturing processes, procedures, documentation and facilities necessary for approval by the FDA or comparable foreign regulatory authorities.

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of approving a BLA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

We intend to seek approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways, if available. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We intend to seek accelerated approval for mecbotamab vedotin, and we may seek accelerated approval for one or more of our other product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful advantage over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. We intend to seek accelerated approval for some of our product candidates on the basis of objective response rate, a surrogate endpoint that we believe is reasonably likely to predict clinical benefit. For products granted accelerated approval, sponsors are required to verify and describe the product's clinical benefit generally in the form of confirmatory trials. These confirmatory trials must be completed with due diligence, and the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. If we were to pursue accelerated approval for a product candidate for a disease or condition, we would likely do so on the basis that there is no available therapy for that disease or condition. If any of our competitors were to receive full approval on the basis of a confirmatory trial for a drug for a disease or condition for which we are seeking accelerated approval before we receive accelerated approval, the disease or condition would no longer qualify as one for which there is no available therapy, and accelerated approval of our product candidate would not occur, unless we were able to demonstrate a meaningful advantage over the approved product. Many cancer therapies rely on accelerated approval, and the treatment landscape can change quickly as the FDA converts accelerated approvals to full approvals on the basis of successful confirmatory trials. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. We cannot assure you that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, we cannot assure you that after subsequent FDA feedback we will continue to pursue accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our product candidates, we cannot assure you that such application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type.

Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, the FDA has convened its Oncologic Drugs Advisory Committee to review what the FDA has called dangling or delinquent accelerated approvals where confirmatory studies have not been completed or where results did not confirm benefit. The enactment of FDORA included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports. In addition, the Oncology Center of Excellence has announced Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post-marketing processes, with the goal to enhance the balance.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we or our existing or future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to conditions of approval, or contain requirements for potentially costly post-marketing testing, including "Phase 4" clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. Furthermore, any regulatory approval to market a product may be subject to limitations on the labeling of the product or may require safety warnings or other restrictions. In addition, the FDA has the authority to require a REMS plan as part of a BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved biologic, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third-party payors.

In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product 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 cGMPs and GCPs for any clinical trials that we conduct post-approval. The manufacturer and manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product;
- withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- delay of approval or refusal by the FDA or comparable regulatory authorities in other jurisdictions to approve pending applications or supplements to approved applications filed by us, our current collaborator or any future strategic partners;
- suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also 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 these regulations impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. 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, which would adversely affect our business, financial condition, results of operations and prospects.

Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time

periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government authorities, private health insurers and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products. If the price we are able to charge for any products we develop, or the reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be adversely affected.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. For example, in the United States, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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.

In some countries, particularly member states of the European Union (EU), the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our existing or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries.

There may be significant delays in obtaining reimbursement for newly approved drugs or therapeutic biologics, and coverage may be more limited than the purposes for which the drug or therapeutic biologic is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for reimbursement does not imply that any drug or therapeutic biologic will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs or therapeutic biologics, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower-cost drugs or therapeutic biologics that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs or therapeutic biologics may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs or therapeutic biologics from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected, and our ability to commercialize such products, once approved, could be materially impaired.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. For example, if we receive marketing approval for mecbotamab vedotin as a treatment for soft tissue and bone sarcoma, physicians may nevertheless use our product for their patients in a manner that is inconsistent with the approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. Moreover, although we believe that our product candidates may be safer or more effective than other therapies, unless we conduct head-to-head comparative studies, we will not be able to make any claims of superiority. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional

conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition, results of operations and prospects.

Disruptions at the FDA, the SEC and other government agencies caused by, among other factors, funding shortages or global health concerns could hinder their ability to hire and retain 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, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, 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, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of the Securities and Exchange Commission, or the SEC, and other government agencies on which our operations may rely, including those 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 new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, notably in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products through April 2020 and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 20, 2020, the FDA announced its intention to resume certain domestic on-site inspections, subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. In addition, on October 26, 2023, the FDA issued a draft guidance document in which the FDA outlined plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where it determines it is appropriate based on mission needs and any travel limitations. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures.

If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We may choose to conduct international clinical trials in the future. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials are performed by clinical investigators of recognized competence and pursuant to current GCP requirements; and (iii) the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. We cannot assure you that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

Our employees, independent contractors, principal investigators, CROs, consultants, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, (ii) manufacturing standards, (iii) federal and state healthcare fraud and abuse laws and regulations or (iv) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial

condition, results of operations and prospects, including the imposition of significant fines or other sanctions, including exclusion from government healthcare programs, and serious harm to our reputation.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In addition, in the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. Previously, in March 2010, the ACA was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Healthcare reform initiatives recently culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which, among other things, allows HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. Only high-expenditure single-source biologics that have been approved for at least 11 years (7 years for drugs) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. Negotiations for Medicare Part D products take place in 2024 with the negotiated price taking effect in 2026, and negotiations for Medicare Part B products will begin in 2026 with the negotiated price taking effect in 2028. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations. HHS will announce the negotiated maximum fair prices by September 1, 2024, and this price cap, which cannot exceed a statutory ceiling price, will go into effect on January 1, 2026. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The negotiated prices will represent a significant discount from average prices to wholesalers and direct purchasers. The law also imposes rebates on Medicare Part D and Part B drugs whose prices have increased at a rate greater than the rate of inflation. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry. It is unclear to what extent other statutory, regulatory, and administrative initiatives will be enacted and implemented, and to what extent these or any future legislation or regulations by the Biden administration or subsequent administrations will have on our business, including market acceptance, and sales, of our products and product candidates.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Beilina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its products available to eligible patients as a result of the Right to Try Act.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological 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. For example, the FDA released a final rule in September 2020 providing guidance for states to build and submit plans for importing drugs from Canada, and FDA authorized the first such plan in Florida in January 2024. 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 drug products that we successfully commercialize or put pressure on our product pricing. 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. These measures could reduce the ultimate demand for our products, once approved, 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 amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current product candidates and any future product candidates or additional pricing pressures.

Our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting and health information privacy and security laws, which could expose us to significant losses, including, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims and civil monetary penalties laws, including the U.S. federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, which imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers;
- the U.S. Physician Payments Sunshine Act created under the ACA, and its implementing regulations, which require that certain manufacturers of drugs, devices, medical supplies and therapeutic biologics that are reimbursable under Medicare, Medicaid, and Children's Health Insurance Programs report annually to the Department of Health and Human Services information related to certain payments and other transfers of value to physicians, as defined by such law, physician assistants, certain types of advance practice nurses and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require that pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug and therapeutic biologics manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures, and information related to drug pricing, including price increases. State and local laws require the registration of pharmaceutical sales representatives.

Foreign and state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection and use of health data in the EU is governed by the General Data Protection Regulation, or the GDPR, which extends the geographical scope of EU data protection law to non-EU entities under certain conditions, tightens existing EU data protection principles and creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we possess and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. We comply with the GDPR and the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in United Kingdom national law, the latter regime having the ability to separately fine and penalize violations. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Ongoing developments in the United Kingdom have created additional uncertainty regarding personal data transfers from the European Economic Area (EEA) to the United Kingdom following the termination of the personal data transfer grace period set out in the EU and United Kingdom Trade and Cooperation Agreement, which ended on June 30, 2021. It is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from EU member states to the

United Kingdom long term without additional measures. Moreover, in July 2020 the Court of Justice of the European Union (CJEU) invalidated the EU-US Privacy Shield Framework (Privacy Shield) under which personal data could be transferred from the EEA and the United Kingdom to entities in the United States who had self-certified under the Privacy Shield scheme. This has led to uncertainty about the adequate transfer mechanisms for other personal data transfers from the EEA and the United Kingdom to the United States or interruption of such transfers. In the event that any court of law orders the suspension of personal data transfers to or from a particular jurisdiction this could give rise to operational interruption in the performance of services for customers, greater costs to implement alternative data transfer mechanisms that are still permitted, regulatory liabilities or reputational harm.

In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the CCPA, as modified by the CPRA, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA and CPRA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states. In addition, Virginia's Consumer Data Protection Act, which took effect on January 1, 2023, requires businesses subject to the legislation to conduct data protection assessments in certain circumstances and requires opt-in consent from consumers to acquire and process their sensitive personal information, which includes information revealing a consumer's physical and mental health diagnosis and genetic and biometric information that can identify a consumer. Colorado enacted the Colorado Privacy Act, and Connecticut enacted the Connecticut Data Privacy Act, each of which took effect on July 1, 2023, and Utah enacted the Consumer Privacy Act, which became effective on December 31, 2023, and each of these laws may increase the complexity, variation in requirements, restrictions, and potential legal risks, and could require increased compliance costs and changes in business practices and policies. Other states have also enacted, proposed, or are considering proposing, data privacy laws, which could further complicate compliance efforts, increase our potential liability and adversely affect our business.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare, privacy and securities laws and regulations worldwide will involve substantial costs. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to regulatory investigations and enforcement actions, as well as civil private plaintiff litigation, which could mean significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from participation in government-funded healthcare programs such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, imprisonment, reputational harm and diminished profits. Responding to regulatory inquiries and defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

If we fail to comply with U.S. and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we may receive and subject us to other penalties that could materially harm our business.

Even if we receive marketing and commercialization approval of a product candidate, we will be subject to continuing regulatory requirements, including in relation to adverse patient experiences with the product and clinical results that are reported after a product is made commercially available, both in the United States and any foreign jurisdiction in which we seek regulatory approval. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The manufacturer and manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. We rely, and expect we will continue to rely, on third-party manufacturers, and we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. If we or our existing or future collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunctions, civil penalties and criminal prosecution.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations may require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

We and our third-party contractors must comply with environmental, health and safety laws and regulations. A failure to comply with these laws and regulations could expose us to significant costs or liabilities.

We and our third-party contractors are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In the event of contamination or injury, or failure to comply with environmental, health and safety laws and regulations, we could be held liable for any resulting damages, fines and penalties associated with such liability which could exceed our assets and resources.

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 biological or hazardous materials or wastes arising out of and in the course of employment, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Environmental, health and safety laws and regulations are becoming increasingly more stringent. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks related to employee matters, managing our growth and other risks related to our business

If we fail to attract and retain qualified senior management and key clinical and scientific personnel, our business may be materially and adversely affected.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and clinical and scientific personnel. We are highly dependent upon members of our senior management, including Jay M. Short, Ph.D., our Chairman and Chief Executive Officer, as well as our clinical development leaders, senior scientists, and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, the initiation and completion of our planned clinical trials or the commercialization of product candidates or any future product candidates.

Competition for qualified personnel in the pharmaceutical, biopharmaceutical and biotechnology field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

We currently have no sales organization. If we are unable to establish sales, marketing and distribution capabilities on our own or through third parties, we may not be able to market and sell our product candidates, if approved, effectively in the United States and foreign jurisdictions or generate product revenue.

We currently do not have a marketing or sales organization. In order to commercialize our product candidates in the United States and foreign jurisdictions on our own, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If any of our product candidates receives regulatory approval, we will need to develop internal sales, marketing and distribution capabilities to commercialize such products, which would be expensive and time-consuming, or make arrangements with third parties to perform these services. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products or decide to co-promote products with existing or future collaborators, we will need to establish and maintain marketing and distribution arrangements with third parties, and we cannot assure you that we will be able to enter into such arrangements on acceptable terms, or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties, and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance of any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2023, we had 65 employees, and 21 dedicated independent contractors based in China and engaged through our agreement with BioDuro-Sundia, a provider of preclinical development services. In order to successfully implement our development and commercialization plans and strategies, and operate as a public company, we expect to need additional development, managerial, operational, financial, sales, marketing and other personnel. Future growth would impose significant added responsibilities on members of management, including, among others:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory review process for mecbotamab vedotin, ozuriftamab vedotin, evalstotug, BA3182, and any other product candidates, 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 successfully develop and, if approved, commercialize mecbotamab vedotin, ozuriftamab vedotin, evalstotug, BA3182, and any future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also 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.

To date, we have used the services of outside vendors to augment our capabilities in performing certain tasks, including preclinical and clinical trial management, manufacturing, statistics and analysis and research and development functions. Our growth strategy may also entail expanding our group of such contractors or consultants to assist in implementing these tasks going forward. Because we rely on numerous consultants, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, 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 regulatory approval for mecbotamab vedotin, ozuriftamab vedotin, evalstotug, BA3182, and any future product candidates or otherwise advance our business. We may not be able to manage our existing outside contractors 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 mecbotamab vedotin, ozuriftamab vedotin, evalstotug, BA3182, and any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may violate (intentionally or unintentionally) our internal processes and procedures, or engage in misconduct or other illegal activity. Such actions could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (1) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, including cGMP requirements, (3) data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify, prevent and deter these activities and/or misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be

effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such actions, including fraud or other misconduct, even if none occurred. If any such actions are instituted against us, we may incur significant costs to respond, and if we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We depend on our information technology systems and those of our CROs, manufacturers, contractors and consultants. Our internal computer systems, such as our enterprise resource planning ("ERP") system, or those of any of our CROs, manufacturers, other contractors, consultants, existing or future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use or acquisition of or destruction of our proprietary and confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our reputation and material disruption of our operations.

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. Despite the implementation of security measures, our internal computer systems and infrastructure and those of our current and any future CROs, manufacturers, other contractors, consultants, existing or future collaborators and other third-party service providers are vulnerable to unauthorized access, impairment, or damage from various methods, including cybersecurity attacks, ransomware attacks, breaches, intentional or accidental mistakes or errors, or other technological failures, which can include, among other things, computer viruses, malware, exploit of unpatched product or service vulnerabilities, unauthorized access attempts (including third parties gaining access to systems using stolen or inferred credentials), denial-of-service attacks, phishing attempts, service disruptions, natural disasters, fire, terrorism, war and telecommunication and electrical failures. As the cyber-threat landscape evolves, these attacks are growing in frequency, levels of persistence, sophistication and intensity, are becoming increasingly difficult to detect, and are being conducted by sophisticated groups and individuals with a wide range of motives and expertise. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. If such an event were to occur and cause interruptions in our operations, impact to critical data or systems, or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy, cybersecurity or data protection laws such as HIPAA, HITECH, the CCPA and GDPR), it could result in a material disruption of our product candidate development programs and our business operations and we could incur significant liabilities. There also could be requirements that we notify individuals and regulators in the event of unauthorized access to, acquisition, destruction, alteration, or misuse of, personal or health information, which could result from breaches experienced by us or by our vendors, contractors or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs, and result in the loss of confidence by our partners, customers, and stakeholders, and thereby have longer term adverse impact on our business operations and revenue. For example, the loss of clinical trial data from completed, ongoing or future clinical trials involving our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. In addition, because of our approach of running multiple clinical trials in parallel, any breach of our computer systems may result in a loss of data or compromised data integrity across many of our programs in various stages of development.

We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed and we could be subject to significant fines or penalties for any noncompliance with certain state, federal or international privacy and security laws.

We operate our ERP system and other key business systems on SaaS platforms. Accordingly, we depend on these systems, and the third-party providers of these services, for a number of aspects of our operations. If these service providers or these systems fail, or if we are unable to continue to have access to these systems on commercially reasonable terms, or at all, operations could be severely disrupted until an equivalent system(s) could be identified, licensed or developed, and integrated into our operations. This disruption could have a material adverse effect on our business.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

A portion of our research and development activities take place in China. Uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations, a trade war, deterioration of international relations, or political unrest in China could materially adversely affect our business, financial condition and results of operations.

We conduct preclinical research and development activities in China through BioDuro-Sundia, which is U.S. owned, but governed by Chinese laws, rules and regulations. Additionally, our agreement with Himalaya Therapeutics Limited Company is for the initiation of clinical trials of evalstotug in the People's Republic of China. The Chinese legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value. In addition, the Chinese legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or not published at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation. Any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since Chinese administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in U.S. or EU legal systems.

Furthermore, we are exposed to the possibility of disruption of our research and development activities in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China, including the escalation of tensions between China and Taiwan, such as recent step up of military exercises around Taiwan by China. In addition, disagreements between the United States and China with respect to their political, military or economic policies toward Taiwan may contribute to further controversies. For example, a trade war could lead to increased costs for clinical materials that are manufactured in China. These interruptions or failures and any restrictive measures resulting from a deterioration of U.S.- China relations could also result in impeding the commercialization of our product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. These uncertainties may impede our ability to enforce the contracts we have entered into and our ability to continue our research and development activities and could materially and adversely affect our business, financial condition and results of operations.

Our current operations are concentrated in two locations. We or the third parties upon whom we depend may be adversely affected by earthquakes, wildfires or other natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

A portion of our current operations are located in our facilities in San Diego, California, and we conduct a portion of our research and development activities in China through our arrangement with BioDuro-Sundia. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes, wildfires or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects. In addition, all of our therapeutic antibodies are manufactured by starting with cells from a master cell bank which are stored in multiple locations to reduce the risk of loss. While we believe we will have adequate backup should any cell bank be lost in a catastrophic event, and we take precautions when transporting our cell banks, it is possible that we could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks.

Our business is subject to economic, political, regulatory and other risks associated with conducting business internationally.

We, our collaborators or licensees may seek regulatory approval of our product candidates outside of the United States including in China, the EU, Australia, New Zealand, and Japan. Additionally, pursuant to our agreement with Himalaya Therapeutics Limited Company, we conduct clinical trials in the People's Republic of China. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including, among others:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

Additionally, in February 2022, armed conflict escalated between Russia and Ukraine, and in October 2023, armed conflict escalated between Israel and Hamas, including in the Gaza Strip. It is not possible to predict the broader consequences of these conflicts, which could include further sanctions, embargoes, greater regional instability, geopolitical shifts and other adverse effects on macroeconomic conditions, currency exchange rates, supply chains and financial markets. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We face risks related to health epidemics and outbreaks, including the COVID-19 pandemic, which could significantly disrupt our preclinical studies, affect enrollment of patients in our clinical trials or delay or prevent our receipt of necessary regulatory approvals.

We face risks related to health epidemics or outbreaks of communicable diseases. The outbreak of communicable diseases could result in a widespread health crisis that could adversely affect general commercial activity and the economies and financial markets of many countries, which in the case of COVID-19 has occurred. Although the U.S. federal government has declared an end to the public health emergency related to the COVID-19 pandemic and many activities worldwide have returned to normal, the COVID-19 pandemic in the past has resulted in, and in the future may result in, governments implementing numerous containment measures, such as travel bans and restrictions, particularly quarantines, shelter-in-place or total lock-down orders and business limitations and shutdowns.

We are following, and plan to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. We are complying with all applicable guidelines for our clinical trials, including remote clinical monitoring. We are continuing to monitor the potential impact of the pandemic, but even though many restrictions aimed at minimizing the spread of COVID-19 have been eased or lifted in the U.S. and other countries, we cannot be certain what the overall impact will be on our business, financial condition, results of operations and prospects.

In addition, the COVID-19 pandemic in the past has had, and in the future may have, a severe effect on the clinical trials of many drug candidates of several sponsors. The extent to which the COVID-19 pandemic may impact our preclinical and clinical trial operations is uncertain and will depend on future developments, including the severity and duration of any resurgence of COVID-19 and its variants. To date, we have experienced modest business disruptions, including with respect to the clinical trials we are conducting, and non-material impairments as a result of the pandemic. A resurgence of COVID-19 or any of its variants could adversely impact our clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Disruptions or restrictions on our ability to travel to monitor data from our clinical trials, or to conduct clinical trials, or the ability of patients enrolled in our studies to travel, or the ability of staff at study sites to travel, as well as temporary closures of our facilities or the facilities of our clinical trial partners and their contract manufacturers, would negatively impact our clinical trial activities. In addition, we rely on independent clinical investigators, CROs and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, including the collection of data from our clinical trials, and an outbreak may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us. Similarly, our preclinical trials could be delayed and/or disrupted by the COVID-19 pandemic. As a result, the expected timeline for data readouts of our preclinical studies and clinical trials and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks related to our dependence on third parties

We have entered, and may in the future seek to enter, into collaborations with third parties for the development and commercialization of certain of our product candidates. If we fail to enter into such collaborations, or such collaborations are not successful, we may not be able to capitalize on the market potential of our patented technology platform and resulting product candidates.

We have entered, and may in the future seek to enter, into collaborations with third parties for the development and commercialization of certain of our product candidates. In addition, we are currently exploring potential third-party collaborators for development and commercialization of select CAB product candidates. With respect to our collaborations, and what we expect will be the case with any future license or collaboration agreements, we have, and would expect to have, limited control over the amount and timing of resources that our existing or future collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our existing or future collaborators' willingness to select additional product candidates to license and their abilities and willingness to fulfill their payment obligations and successfully perform the functions assigned to them in these arrangements.

Our existing collaboration arrangements currently pose, and future collaborations involving our product candidates will pose, the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on preclinical or clinical trial results, changes in the collaborators' strategic focus due to their acquisition of competitive products or their internal development of competitive products, available funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators and other alliances could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidate, particularly if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidate or that result in costly litigation or arbitration that diverts management attention and resources;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations;
- collaborators may not provide us with timely and accurate information regarding development, regulatory or commercialization status or results, which could adversely impact our ability to manage our own development efforts, accurately forecast financial results or provide timely information to our stockholders regarding our out-licensed product candidates;
- collaborations may be terminated and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates; and
- collaborators' sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If our existing or future collaborators cease development efforts under our existing or future collaboration agreements, or if any of those agreements are terminated, we may lose committed funding under those agreements and these collaborations may fail to lead to commercial products and the reputation of our patented CAB technology platform may suffer.

Revenue from research and development collaborations depend upon continuation of the collaborations, initiation and expansion of the number of programs subject to the collaborations, the achievement of milestones and royalties, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates or achieve milestones, revenue and cash resources from milestone payments under our existing or future collaboration agreements will be substantially less than expected.

Our ability to advance our product candidates may be limited by third parties on which we rely for certain technologies which we use in certain of our programs. If any third party developing our product candidates or other candidates based on our patented CAB technology platform experiences a delay or failure in development, regulatory approval or commercialization, even if such failure is not due to our CAB technology, it could reflect negatively on us, our other product candidates and our patented CAB technology platform. In addition, if one of our current or future collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities and our stock price could be adversely affected.

We may not be successful in establishing commercialization collaborations, which could adversely affect our ability to commercialize our product candidates, if approved.

From time to time, we may evaluate and, if strategically attractive, seek to enter into additional collaborations, including with major biotechnology or biopharmaceutical companies. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for

example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the collaborator terminates the collaboration. Moreover, such arrangements are complex and time-consuming to negotiate, document and implement and they may require substantial resources to maintain.

In addition, it is possible that a collaborator may not devote sufficient resources to the commercialization of our product candidates or may otherwise fail in its commercialization efforts, in which event the commercialization of such product candidates could be delayed or terminated and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not be favorable to us or may not be perceived as favorable, which may negatively impact our business, financial condition, results of operations and prospects.

If third parties on which we rely to conduct our preclinical and clinical trials, do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development programs could be delayed with material and adverse effects on our business, financial condition, results of operations and prospects.

We rely, and expect we will continue to rely, on third-party investigators, CROs, data management organizations and consultants to conduct, supervise and monitor our ongoing clinical trials and preclinical studies. Because we rely on these third parties and do not have the ability to conduct preclinical studies or clinical trials independently, we have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants are not our employees and we will have limited control over the amount of time and resources that they dedicate to our development programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our development programs. The third parties with whom we contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we do not contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our development programs could be delayed and otherwise adversely affected. Furthermore, we depend on the availability of various animals to conduct certain preclinical studies that we are required to complete prior to submitting an IND and initiating clinical development or to continue clinical development, including pharmacological and toxicology evaluations. There is currently a shortage of animals available for drug development due to an increase in demand from companies conducting research in the U.S., EU, and China. This has caused the cost of obtaining animals for our preclinical studies to increase dramatically, and if the shortage continues, could also result in delays to our development timelines. In all events, we are responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan, protocols for the trial and regulatory requirements. The FDA requires preclinical studies to be conducted in accordance with GLPs and clinical trials to be conducted in accordance with GCPs, including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Any adverse development or delay in our preclinical studies and clinical trials could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Additionally, in January 2024, there was congressional activity, including the introduction of the BIOSECURE Act in the House of Representatives and a substantially similar Senate bill. If these bills became law, or similar laws are passed, they would have the potential to severely restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies "of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We do some business with companies in China and it is possible some of our contractual counterparties could impacted by the legislation described above.

We rely on third parties for the manufacture of our product candidates for preclinical studies and our ongoing clinical trials, and we expect to continue to do so for additional clinical trials and ultimately commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We rely, and expect we will continue to rely, on third-party contract manufacturers to manufacture our preclinical and clinical trial product supplies and the raw materials used to create our product candidates. We do not own manufacturing facilities for producing such supplies, and we do not have long-term manufacturing agreements. Furthermore, the raw materials for our product candidates may be sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. We cannot assure you that our preclinical and clinical development product supplies or raw materials will not be limited, interrupted, or be of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of a manufacturer could require significant effort and expertise because there are a limited number of qualified replacements. The technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates.

If we submit an application for regulatory approval of any of our product candidates, the facilities used by our contract manufacturers to manufacture our product candidates will be subject to inspection by the FDA or other regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others or if they are

unable to maintain a compliance status acceptable to the FDA or other regulatory authorities, approval of our product candidates may be delayed or 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, if approved.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

In addition, we have no material long-term contracts with our suppliers, and we compete with other companies for raw materials and production. We may experience a significant disruption in the supply of raw materials from current sources or, in the event of a disruption, we may be unable to locate alternative materials suppliers of comparable quality at an acceptable price, or at all. In addition, if we experience significant increased demand, or if we need to replace an existing supplier, we may be unable to locate additional supplies of raw materials on terms that are acceptable to us, or at all, or we may be unable to locate any supplier with sufficient capacity to meet our requirements or to fill our orders in a timely manner. Identifying a suitable supplier is an involved process that requires us to become satisfied with their quality control, responsiveness and service, financial stability and labor and other ethical practices. Even if we are able to expand existing sources, we may encounter delays in production and added costs as a result of the time it takes to train suppliers in our methods, products and quality control standards.

The manufacture of biotechnology products is complex, and manufacturers often encounter difficulties in production. If we or any of our third-party manufacturers encounter any loss of materials or if any of our third-party manufacturers encounter other difficulties, or otherwise fail to comply with their contractual or regulatory obligations, our ability to provide product candidates for clinical trials or our products to patients, once approved, the development or commercialization of our product candidates could be delayed or stopped.

The manufacture of biotechnology products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and our contract manufacturers must comply with cGMPs, regulations and guidelines for the manufacturing of biologics used in clinical trials and, if approved, marketed products. In order to conduct clinical trials of our product candidates, we and existing and future collaborators will need to manufacture them in large quantities and in accordance with cGMPs. Manufacturers of biotechnology products often encounter difficulties in production, particularly in scaling up and validating initial production. In addition, 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. Delays in raw materials availability and supply may also extend the period of time required to develop our products. Furthermore, changes in our manufacturing methods may require comparability studies, including clinical bridging studies, which may result in delays to the approval process for our product candidates.

All of our therapeutic antibodies are manufactured by starting with cells from a cell bank. In accordance with cGMPs, we produce one master cell bank for each antibody manufactured, which is then stored in multiple locations to reduce the risk of loss. We have also created a working cell bank for certain manufactured antibodies. While we believe we will have adequate backup should any cell bank be lost in a catastrophic event, and we take precautions when transporting our cell banks, it is possible that we could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks.

We cannot assure you that any stability or other issues relating to the manufacture of any of our product candidates or products will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. For example, the extent to which the COVID-19 pandemic impacts the ability to procure sufficient supplies for the development of our product candidates will depend on future developments, including the severity and duration of any resurgence of COVID-19 and its variants. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual

obligations, our ability to provide any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products or enforcement actions by regulatory authorities. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products and could have an adverse effect on our business, financial condition, results of operations and prospects.

Risks related to intellectual property

If we are not able to obtain, maintain and protect our intellectual property rights in any product candidates or technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, third parties could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market.

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, methods used to develop and manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. The patent process is expensive and time-consuming, and we may not be able to apply for patents on certain aspects of our product candidates in a timely fashion, at a reasonable cost, in all jurisdictions, or at all. Our existing issued and granted patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable or that any issued or granted patents will include claims that are sufficiently broad to cover our product candidates or to provide meaningful protection from our competitors.

Moreover, the patent position of biotechnology and biopharmaceutical companies can be highly uncertain because it involves complex legal and factual issues. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our position in the market. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our patent claims.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against granted patents. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted patent claims thus attacked, or may lose the allowed or granted claims altogether. In the past we have been party to a patent opposition proceeding at the European Patent Office, or EPO, and we may in the future become party to patent opposition proceedings in the EPO or similar proceedings in other foreign patent offices. In addition, we cannot assure you that:

- We may obtain, maintain, protect and enforce intellectual property protection for our technologies and product candidates.
- Others will not or may not be able to make, use or sell compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or license.
- We or our licensors, or our existing or future collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license.
- We or our licensors, or our existing or future collaborators are the first to file patent applications covering certain aspects of our inventions.
- Others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- A third party may not challenge our patents and, if challenged, that a court would hold that our patents are valid, enforceable and infringed.
- Any issued patents that we own or have licensed will provide us with any competitive advantage or will not be challenged by third parties.
- We may develop or in-license additional proprietary technologies that are patentable.
- Pending patent applications that we own or may license will lead to issued patents.
- The patents of others will not have a material or adverse effect on our business, financial condition, results of operations and prospects.

- Our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our commercial markets.

If the breadth or strength of protection provided by the patents and patent applications we hold, obtain or pursue with respect to our product candidates is challenged, or if they fail to provide meaningful exclusivity for our product candidates, it could threaten our ability to practice our technologies or commercialize our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Furthermore, an interference or derivation proceeding can be provoked by a third party or instituted by a patent office or in a court proceeding, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

Where we obtain licenses from third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. We may also require the cooperation of our licensors to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license could have a material adverse impact on our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for certain aspects of our product candidates, we also consider trade secrets, including confidential and unpatented know-how important to the maintenance of our competitive position. We seek to protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position could be harmed.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. Competitors could willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products, others may be able to exploit our product candidates and discovery technologies to identify and develop competing product candidates, and thus our competitive position could be adversely affected, as could our business.

The terms of our patents may not protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years after its earliest U.S. non-provisional effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our technologies or product candidates are obtained, once the patent life has expired, we may be open to competition. Our issued patents will expire on dates ranging from 2030 to 2040, subject to any additional patent extensions that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2030 to 2043 plus any potential patent extensions that may be available for such patents. Due to 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 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 our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or 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. A maximum of one patent may be extended per FDA-approved product as compensation for the 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 and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request or require. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request or require, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In September 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether another party was first to invent the claimed invention. A third party that filed or files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art render our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and the provision of additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of the application of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard applied in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution and defense of our or our licensors' 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.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, sometimes narrowing the scope of patent protection available in certain circumstances, or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and the patents we might obtain or license in the future.

Other companies or organizations may challenge our or our licensors' patent rights or may assert patent rights that prevent us from developing and commercializing our products.

CAB therapeutics are a new scientific field. We have obtained grants and issuances of CAB therapeutic patents and the various technologies used in discovering and producing CAB therapeutic proteins. The issued patents and pending patent applications in the United States and in key markets around the world that we own or license claim many different methods, compositions and processes relating to the discovery, development, manufacture and commercialization of antibody and immunoregulatory therapeutics. Specifically, we own a portfolio of patents, patent applications and other intellectual property covering CAB compositions of matter as well as their development and methods of use.

As the field of antibody and immunoregulatory therapeutics matures, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, as to when, to whom, and with what claims. In addition, third parties may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material and adverse effect on our business, financial condition, results of operations and prospects or our ability to successfully compete.

There are many issued and pending patents that claim aspects of our product candidates and modifications that we may need to apply to our product candidates. There are also many issued patents that claim antibodies or portions of antibodies that may be relevant for CAB products we wish to develop. Thus, it is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may not be able to market products or perform research and development or other activities covered by these patents.

Intellectual property rights of third parties could prevent or delay our drug discovery and development efforts and could adversely affect our ability to commercialize our product candidates, and we might be required to litigate or obtain licenses from third parties in order to discover, develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing or otherwise violating the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation proceedings, post grant reviews, *inter partes* reviews, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Given the vast number of patents in our field of technology, we cannot assure you that marketing of our product candidates or practice of our technologies will not infringe existing patents or patents that may be granted in the future. Because the antibody landscape is still evolving and the CAB antibody landscape is a new field, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. There are numerous companies that have pending patent applications and issued patents broadly covering many aspects of antibodies generally or covering antibodies directed against the same targets as, or targets similar to, those we are pursuing. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our products or product candidates or elements thereof, or our manufacture or uses relevant to our development plans. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product or formulation itself, the holders of any such patents may be able to block our ability to commercialize such product candidate. In such cases, we may not be in a position to develop or commercialize products or product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further practice our technologies or develop and commercialize one or more of our product candidates. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our CAB technologies. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our CAB technologies. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, be forced to abandon our product candidates or seek a license from any patent holders, and would most likely be required to pay license fees or royalties or both, each of which could be substantial. No assurances can be given that a license will be available on commercially reasonable terms, if at all. Even if we were able to obtain a license, the rights we obtain may be nonexclusive, which would provide our competitors access to the same intellectual property rights upon which we are forced to

rely. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates or technologies may give rise to claims of infringement of the patent rights of others.

We or our collaboration partner, or any future strategic partners may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. If we or our licensors, or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay damages, potentially including treble damages, if we are found to have willfully infringed. In addition, we or our licensors, or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we or our existing or future collaborators may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, U.S. applications filed before November 29, 2000, and certain U.S. applications filed after that date that will not be filed outside the United States, remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates or technologies could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products. Third-party intellectual property right holders may also actively bring infringement claims against us, even if we have received patent protection for our technologies and product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our products. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates or our technologies so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may have ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful, and issued patents covering our product candidates could be found invalid or unenforceable if challenged in court in the United States or abroad.

Competitors may infringe our patents or the patents of our licensors. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products or our technology, the defendant could counterclaim that our patent is invalid or unenforceable, or the court may refuse to stop the defendant in such infringement proceeding from using the technology at issue on the grounds that our patents do not cover the technology in question. 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, for example, lack of

novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have a material and adverse effect on our business, financial condition, results of operations and prospects. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights.

Interference or derivation proceedings provoked by third parties or brought by us, the USPTO or any foreign patent authority may be necessary to determine the priority and/or ownership of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property, trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

Obtaining a valid and enforceable issued or granted patent covering our technology in the United States and worldwide can be extremely costly. In jurisdictions where we have not obtained patent protection, competitors may use our technology to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where it is more difficult to enforce a patent as compared to the United States. Competitor products may compete with our future products in jurisdictions where we do not have issued or granted patents or where our issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly that relating to biopharmaceuticals. This could make it difficult for us to prevent the infringement of our patents or marketing of competing products in violation of our proprietary rights in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions, regardless of whether they are successful, could result in substantial cost and divert our efforts and attention from other aspects of our business. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

We generally file a provisional patent application first (a priority filing) at the USPTO. An international application under the Patent Cooperation Treaty, or PCT, is usually filed within 12 months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in the United States, Europe, Japan, Australia and Canada and, depending on the individual case, also in any or all of, *inter alia*, Brazil, China, Hong Kong, India, Israel, Mexico, New Zealand, Russia, South Africa, South Korea and other jurisdictions. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted in other jurisdictions. It is also quite common that depending on the country, various scopes of patent protection may be granted on the same product candidate or technology. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The requirements for patentability differ, in varying degrees, from country to country, and the laws of some foreign countries do not protect intellectual property rights, including trade secrets, to the same extent as federal and state laws of the United States. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. 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 are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business and results of operations may be adversely affected.

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

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time-consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to 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. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. 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.

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates or we could lose certain rights to grant sublicenses.

Our current and any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement and/or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements. We also may be unable to license or acquire third-party intellectual property rights on terms that that would be favorable to us or would allow us to make an appropriate return on our investment. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ reputable law firms and other professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and if we in-license intellectual property we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. 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. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and biopharmaceutical patents. As such, we do not know the degree of future protection that we will have on our technologies and product candidates. While we will endeavor to try to protect our technologies and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and sometimes unpredictable.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing, our product candidates, which could severely harm our business. Even if we are successful in defending against these 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.

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We only have one currently registered trademark, and rely on common law protection for the rest of our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Risks related to our common stock

Our operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to annual and quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including, among others:

- variations in the level of expense related to the ongoing development of our product candidates or future development programs;
- results of preclinical studies and clinical trials, or the addition or termination of clinical trials;
- the success of our existing collaborations and any potential additional collaborations, licensing or similar arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- 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;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Our stock price may be volatile, and you could lose all or part of your investment.

The trading price of our common stock has been and is likely to continue to be highly volatile. The market price for our common stock may be influenced by many factors, including the other risks described in this section and the following:

- the timing and results of our clinical trials or those of our competitors;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our current or future collaborators or our competitors, and the timing of these introductions or announcements;

- announcements of new collaboration agreements, or the restructuring or termination of current collaboration agreements;
- actions taken by regulatory agencies with respect to our products, preclinical studies, clinical trials, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including those regarding manufacturing, supply and commercialization of our products;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analysts' recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our common stock;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- the impact of any natural disasters or public health emergencies, such as the COVID-19 pandemic; and
- general economic, industry and market conditions.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

The future issuance of equity or of debt securities that are convertible into equity will dilute our share capital.

We will need to raise additional capital in the future. To the extent we raise additional capital through the issuance of equity or convertible debt securities in the future, there will be further dilution to investors and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. We may choose to raise additional capital through the issuance of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock.

If securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading research or reports regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us, our business or our market. If no or few securities or industry analysts commence or maintain coverage of us, the trading price for our stock would be negatively impacted. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our

intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval and their interests may conflict with your interests as an owner of our common stock.

As of December 31, 2023, executive officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially own approximately 36.5% of our outstanding common stock. More specifically, Jay M. Short, Ph.D, our Chairman and Chief Executive Officer, together with his spouse, beneficially own approximately 6.4%, of our outstanding common stock, as of December 31, 2023.

As a result, Dr. Short and our other principal stockholders will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

In addition, we have entered into certain related party transactions with Himalaya Therapeutics SEZC, Inversagen, LLC and BioAtla Holdings, LLC, including various licensing arrangements with respect to certain CAB antibodies. Dr. Short and his spouse are each a manager of Inversagen, LLC and BioAtla Holdings, LLC and a director of Himalaya Therapeutics SEZC. In addition, Dr. Short's spouse is also an officer of Himalaya Therapeutics SEZC. These related party transactions, and any future related party transactions, create the possibility of actual conflicts of interest with regard to Dr. Short.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

All of our outstanding shares of common stock are freely tradable without restriction or further registration under the Securities Act unless held by our "affiliates" as defined in Rule 144 under the Securities Act, or Rule 144. Shares issued upon the exercise of stock options and warrants outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by Rules 144 and 701 under the Securities Act.

We registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, which shares will be able to be sold in the public market upon issuance, subject to applicable securities laws.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in the amended and restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. In addition, 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. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- a requirement that special meetings of stockholders be called only by the chairman of our board of directors, our chief executive officer, or our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- advance notice requirements for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings;
- a requirement that directors may only be removed "for cause" and only with 66 2/3% voting stock of our stockholders;
- a requirement that only the board of directors may change the number of directors and fill vacancies on the board;
- division of our board of directors into three classes, serving staggered terms of three years each; and
- the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, as amended, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions would apply even if the proposed merger or acquisition could be considered beneficial by some stockholders.

The Company's ability to attract and retain qualified members of our board of directors may be impacted due to new state laws, including recently enacted gender quotas.

In September 2018, California enacted SB 826 requiring public companies headquartered in California to maintain minimum female representation on their boards of directors as follows: by the end of 2019, at least one woman on its board, by the end of 2020, public company boards with five members will be required to have at least two female directors, and public company boards with six or more members will be required to have at least three female directors.

In September 2020, California enacted AB 979, which requires that by the end of 2021 California-headquartered public companies have at least one director on their boards who is from an underrepresented community, defined as "an individual who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, or Alaska Native, or who self-identifies as gay, lesbian, bisexual, or transgender."

In addition to that initial 2021 requirement, the law mandated that the number of directors from underrepresented communities be increased by the end of calendar year 2022, depending on the size of the board.

In addition, the Company is subject to the listing rules from Nasdaq related to board diversity and disclosure, which require all companies listed on Nasdaq's U.S. exchanges to publicly disclose consistent, transparent diversity statistics regarding their board of directors. Additionally, the rules require most Nasdaq-listed companies to have, or explain why they do not have, at least two diverse directors, including one who self-identifies as female and one who self-identifies as either an underrepresented minority or LGBTQ+.

Failure to achieve designated minimum gender and diversity levels in a timely manner exposes such companies to financial penalties and reputational harm. While we are currently in compliance with these regulations, we cannot assure that we can recruit, attract and/or retain qualified members of the board and meet gender and diversity quotas as a result of the California laws or Nasdaq rules, which may expose us to penalties and/or reputational harm.

We have incurred, and will continue to incur, significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices. Additionally, if we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Also, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities, including obtaining director and officer liability insurance, and maintaining such coverage, more time-consuming and costly. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors or our board committees or as executive officers. However, 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.

In addition, as a public company, we are required to incur costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting, and if we cease to be a smaller reporting company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We engaged outside consultants to assist in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have dedicated, and will continue to dedicate, internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting. As a result of the complexity involved in complying with the rules and regulations applicable to public companies, our management's attention may be diverted from other business concerns, which could harm our business, operating results, and financial condition. Since becoming a public company, we increased, and may in the future further increase, the number of employees dedicated to finance and reporting, and the services of outside consultants to meet requirements, which has increased our operating expenses.

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 to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. Our internal control over financial reporting may not prevent or detect all errors and all fraud.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on The Nasdaq Global Market.

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 facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. 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.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of our common stock, which is not certain.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Regardless of the merits or the ultimate results of such litigation, securities litigation brought against us could result in substantial costs and divert our management's attention from other business concerns.

Our certificate of incorporation and bylaws designate the Court of Chancery of the State of Delaware 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 certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for the following types of proceedings: (i) any derivative action or proceeding brought on behalf of our company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware or as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware or (iv) any action asserting a claim arising pursuant to any provision of our amended and restated certificate of incorporation or amended and restated bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum, to the

fullest extent permitted by law, for resolving any complaint asserting a cause of action arising under the Securities Act. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation and amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation and amended and restated bylaws described above.

ITEM 1B. Unresolved Staff Comments

Not applicable.

ITEM 1C. Cybersecurity

Cybersecurity Risk Management and Strategy:

We recognize the importance of assessing, identifying, and managing material risks associated with cybersecurity threats, as such term is defined in Item 106(a) of Regulation S-K. These risks include, among other things, operational risks; intellectual property theft; fraud; extortion; harm to employees or customers; violation of privacy or security laws and other litigation and legal risk; and reputational risks.

We also maintain an incident response plan to coordinate the activities we take to protect against, detect, respond to and remediate cybersecurity incidents, as such term is defined in Item 106(a) of Regulation S-K, as well as to comply with potentially applicable legal obligations and mitigate brand and reputational damage.

We have implemented several cybersecurity processes, technologies, and controls to aid in our efforts to identify, assess, and manage material risks, as well as to test and improve our incident response plan. Our approach includes, among other things:

- conducting regular network and endpoint monitoring, vulnerability assessments, and penetration testing to improve our information systems, as such term is defined in Item 106(a) of Regulation S-K
- regular cybersecurity training programs for employees and management; and annual cybersecurity management training for employees involved in our systems and processes that handle sensitive data;
- leveraging the NIST incident handling framework to help us identify, protect, detect, respond, and recover when there is an actual or potential cybersecurity incident;
- operating threat intelligence processes designed to research our adversaries;
- closely monitoring emerging data protection laws and implementing changes to our processes designed to comply;
- conducting regular phishing email simulations for all employees and all contractors with access to corporate email systems to enhance awareness and responsiveness to such possible threats;
- through policy, practice, and contract (as applicable) requiring employees, as well as third-parties who provide services on our behalf, to treat sensitive information with care;
- carrying information security risk insurance that provides protection against the potential losses arising from a cybersecurity incident; and
- maintaining a risk management program for suppliers, vendors, and other third parties, which includes conducting pre-engagement risk-based diligence, implementing contractual security and notification provisions, and ongoing monitoring as needed.

These approaches vary in maturity across the business, and we work to continually improve them.

Our process for identifying and assessing material risks from cybersecurity threats operates alongside our broader overall risk assessment process, covering all company risks. As part of this process appropriate disclosure personnel will collaborate with subject matter specialists, as necessary, to gather insights for identifying and assessing material cybersecurity threat risks, their severity, and potential mitigation.

As part of the above approach and processes, we have engaged an assessors to review our cybersecurity program to help identify areas for continued focus, improvement and/or compliance.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading "We depend on our information technology systems and those of our CROs, manufacturers, contractors and consultants. Our internal computer systems, or those of any of our CROs, manufacturers, other contractors, consultants, existing or future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use or acquisition of or destruction of our proprietary and confidential data, employee data or personal data, which could result in additional costs, loss of revenue significant liabilities, harm to our reputation and material disruption of our operations" included as part of our risk factor disclosures at Item 1A of this Annual Report on Form 10-K, and under the heading "Risks related to employee matters, managing our growth and other risks related to our business."

In the last three fiscal years, we have not experienced any material cybersecurity incidents and the expenses we have incurred from cybersecurity incidents were immaterial. This includes penalties and settlements, of which there were none.

Cybersecurity Governance:

Cybersecurity is an important part of our risk management processes and an area of increasing focus for our Board and management. Our Audit Committee is responsible for the oversight of risks from cybersecurity threats. The Audit Committee semi-annually receives an overview from management of our cybersecurity threat risk management and strategy processes covering topics such as data security posture, progress towards pre-determined risk-mitigation-related goals, our incident response plan, and cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. In such sessions, the Audit Committee generally receives materials indicating current and emerging cybersecurity threat risks, and describing the company's ability to mitigate those risks. Members of the Board and the Audit Committee are also encouraged to regularly engage in ad hoc conversations with management on cybersecurity-related news events and discuss any updates to our cybersecurity risk management and strategy programs. Material cybersecurity threat risks may also be considered during separate Board meeting discussions.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by our Senior Vice President of IP and Contracts and other members of the management team. Our team has over ten years in information technology, cybersecurity, risk management, and compliance and includes individuals with BS degrees in Information Technology and several information technology and security certifications.

These members of management are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan. If a cybersecurity incident is determined to be a material cybersecurity incident, our incident response plan and cybersecurity disclosure controls and procedures define the process to disclose such a material cybersecurity incident.

ITEM 2. Properties

Our headquarters are located at 11085 Torreyana Road, San Diego, California 92121, where we lease approximately 43,377 square feet of office and laboratory space under a lease that terminates on February 28, 2025. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

ITEM 3. Legal Proceedings

From time to time, we may be subject to various claims and suits arising in the ordinary course of business. We are not currently a party to any legal proceedings the outcome of which we believe, if determined adversely to us, would individually or in the aggregate have a material adverse effect on our business, operating results or financial condition.

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

Shares of our common stock began trading on the Nasdaq Global Market on December 16, 2020 under the symbol "BCAB." Prior to that time, there was no public market for shares of our common stock.

Holders of Record

As of March 26, 2024, there were 28 stockholders of record of our common stock and 0 stockholders of record of our Class B common stock. These numbers were derived from our stockholder records and do not include beneficial owners of our common stock whose shares are held in "street" name with various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Registered Securities

On December 15, 2020, the SEC declared effective our registration statement on Form S-1 (File No. 333-250093), as amended, filed in connection with our Initial Public Offering ("IPO"). At the closing of the offering on December 18, 2020, we issued and sold 12,075,000 shares of our common stock at the initial public offering price to the public of $18.00 per share, which included the exercise in full of the underwriters' option to purchase additional shares. We received gross proceeds from the IPO of $217.4 million, before deducting underwriting discounts and commissions of approximately $15.2 million and estimated offering costs of approximately $3.8 million. J.P. Morgan, Jefferies and Credit Suisse acted as joint book-running managers for the offering. BTIG acted as co-manager for the offering. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

As of December 31, 2023, we have used all $198.3 million of the proceeds from our IPO. There has been no material change in the planned use of such proceeds from that described in the final prospectus filed by us with the SEC on December 17, 2020.

ITEM 6. [Reserved]

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

You should read the following discussion and analysis together with our financial statements and related notes included in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. For a complete discussion of forward-looking statements, see the section above entitled "Forward-Looking Statements." Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption "Item 1A. Risk Factors."

Overview

We are a clinical-stage biopharmaceutical company developing our novel class of highly specific and selective antibody-based therapeutics for the treatment of solid tumor cancer. Our CABs capitalize on our proprietary discoveries with respect to tumor biology, enabling us to target known and widely validated tumor antigens that have previously been difficult or impossible to target. Our novel CAB therapeutic candidates exploit characteristic pH differences between the tumor microenvironment and healthy tissue. Unlike healthy tissue, the tumor microenvironment is acidic, and we have designed our antibodies to selectively bind to their targets on tumor cells under acidic pH conditions but not on targets in normal tissues. Our approach is to identify the necessary targeting and potency required for cancer cell destruction, while aiming to eliminate or greatly reduce on-target, off-tumor toxicity—one of the fundamental challenges of existing cancer therapies.

We are a United States-based company with research facilities in San Diego, California and, through our contractual relationship with BioDuro-Sundia, a provider of preclinical development services, in Beijing, China. Since the commencement of our operations, we have focused substantially all of our resources on conducting research and development activities, including drug discovery, preclinical studies and clinical trials of our product candidates, including the ongoing Phase 2 clinical trials of mecbotamab vedotin (BA3011), ozuriftamab vedotin (BA3021), and evalstotug (BA3071), and our Phase 1 clinical trial of BA3182 (CAB-EpCAM x CAB-CD3), establishing and maintaining our intellectual property portfolio, manufacturing clinical and research material through third parties, hiring personnel, establishing product development and commercialization collaborations with third parties, raising capital and providing general and administrative support for these operations. Since 2014, such research and development activities have exclusively related to the research, development, manufacture and Phase 1 and Phase 2 clinical testing of our CAB antibody-based product candidates and the strengthening of our proprietary CAB technology platform and pipeline.

We have incurred significant losses to date. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current and future product candidates. Our net losses were $123.5 million and $106.5 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $416.3 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We do not expect to generate meaningful revenue from product sales for the foreseeable future, and we expect to continue to incur significant operating expenses for the foreseeable future due to the cost of research and development, including identifying and designing product candidates and conducting preclinical studies and clinical trials, and the regulatory approval process for our product candidates. We expect our expenses, and the potential for losses, to be variable as we focus development efforts on our prioritized programs. Research and development expenses will vary as we continue to advance clinical trials of our lead product candidates, and will decrease once we complete enrollment and treatment of patients in those trials.

We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities as we:

- advance the clinical development of mecbotamab vedotin;
- advance the clinical development of ozuriftamab vedotin;
- advance the clinical development of evalstotug;
- advance the clinical development of BA3182;
- expand our pipeline of bispecific and other CAB antibody-based product candidates;
- continue to invest in our CAB technology platform;
- maintain, protect and expand our intellectual property portfolio, including patents, trade secrets and know-how;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish additional product collaborations and commercial manufacturing relationships with third parties;
- build sales, marketing and distribution infrastructure and relationships with third parties to commercialize product candidates for which we may obtain marketing approval;
- continue to expand our operational, financial and management information systems; and
- attract, hire and retain additional clinical, scientific, management, administrative and commercial personnel.

As a result, we will require substantial additional capital to develop our product candidates and fund operations for the foreseeable future. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings, debt financings, collaborations and other similar arrangements. The amount and timing of our future funding

requirements will depend on many factors, including the pace and results of our development efforts. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to raise capital, maintain our research and development efforts, expand our business or continue our operations at planned levels, and as a result we may be forced to substantially reduce or terminate our operations.

As of December 31, 2023, our cash and cash equivalents totaled approximately $111.5 million. Based on our current operating plan, our current cash and cash equivalents are expected to be sufficient to fund our ongoing operations for a period of at least twelve months from the date of issuance of the financial statements included in this report. Our current operating plan includes plans to complete enrollment in certain of our clinical trials, delaying development of certain pre-clinical programs, and prioritizing and focusing clinical development on selected assets and indications. In addition, we have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Impact of COVID-19 on our business

The COVID-19 pandemic previously impacted our ongoing operations, including clinical trials. The extent to which the COVID-19 pandemic may continue to impact our business, financial condition and results of operations cannot be reasonably estimated and will depend on future developments, which are highly uncertain and cannot be predicted, including the severity and duration of any resurgence of COVID-19 and its variants and the actions necessary to contain any resurgence or treat its impact, among others. We will continue to monitor the COVID-19 situation closely and operate in accordance with all relevant health and safety guidelines as they evolve in response to changing public health conditions.

Financial operations overview

Revenue

To date, we have not generated any revenue from the sale of products and do not expect to generate meaningful revenue in the near future.

The Company has entered into collaborations and licensing agreements with various third parties that, in some cases, may provide for potential future milestone and royalty payments to us (see Note 7 to our financial statements). Prior to developing our own programs, we received revenue from services performed under fixed price service contracts that, in some cases, provided for potential milestone and royalty payments to us. We did not recognize any revenues from collaborations, licenses, or our legacy service contracts during the years ended December 31, 2023 and 2022, respectively.

Operating expenses

Research and development

Research and development expenses consist primarily of costs incurred in the discovery and development of our product candidates.

- External expenses consist of:
    - Fees paid to third parties such as contractors, clinical research organizations (CROs) and consultants, and other costs related to preclinical and clinical trials;
    - Fees paid to third parties such as contract manufacturing organizations (CMOs) and other vendors for manufacturing research and clinical trial materials; and
    - Expenses related to laboratory supplies and services.
- Unallocated expenses consist of:
    - Personnel-related expenses, including salaries, benefits and equity-based compensation expenses, for personnel in our research and development functions; and
    - Related equipment and facilities depreciation expense.

We expense research and development costs in the periods in which they are incurred. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and services are performed.

We expect our research and development expenses to remain variable from quarter to quarter as we continue to advance our clinical programs, then decreasing after we complete enrollment and treatment in certain of our clinical trials, and focus development on selected high potential indications. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. Successful 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. Accordingly, to the extent that our

product candidates continue to advance into clinical trials, including larger and later-stage clinical trials, our expenses will increase substantially and may become more variable. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, the quality and consistency in their manufacture, investment in our clinical programs and competition with other products. As a result of these variables, we are unable to determine the duration and completion costs of our research and development projects and programs or when and to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for any of our product candidates.

General and administrative

Our general and administrative expenses include personnel-related expenses for personnel in our executive, finance, corporate and other administrative functions, intellectual property and patent costs, facilities and other allocated expenses, other expenses for outside professional services, including legal, human resources, investor relations, audit and accounting services and insurance costs. Personnel-related expenses consist of salaries, benefits and equity-based compensation. We expect our general and administrative expenses to remain flat to moderately increasing in the future to support development of our prioritized CAB programs.

Interest income

Interest income consists primarily of interest earned on our cash and cash equivalent balances.

Results of operations

Comparison of the years ended December 31, 2023 and 2022

	Years Ended December 31,		
	2023	2022	Change
	(in thousands)		
Operating expenses:			
Research and development	103,731	79,347	24,384
General and administrative	25,956	28,793	(2,837)
Total operating expenses	129,687	108,140	21,547
Loss from operations	(129,687)	(108,140)	(21,547)
Other income:			
Interest income	6,312	1,648	4,664
Other income (expense)	(87)	10	(97)
Total other income	6,225	1,658	4,567
Net loss and comprehensive loss	$ (123,462)	$ (106,482)	$ (16,980)

Research and development expense

The following table summarizes our research and development expenses allocated by CAB program for the periods indicated:

	Years Ended December 31,		
	2023	2022	Change
	(in thousands)		
External expenses:			
Mecbotamab vedotin, BA3011 (CAB AXL-ADC)	$ 24,533	$ 17,444	$ 7,089
Ozuriftamab vedotin, BA3021 (CAB ROR2-ADC)	13,530	9,391	4,139
Evalstotug, BA3071 (CAB CTLA-4)	17,099	9,671	7,428
BA3182 (CAB EpCAM x CAB CD3)	4,048	6,161	(2,113)
Other CAB Programs	22,159	17,321	4,838
Total external expenses	81,369	59,988	21,381
Personnel and related	12,552	10,758	1,794
Equity-based compensation	5,462	5,419	43
Facilities and other	4,348	3,182	1,166
Total research and development expenses	$ 103,731	$ 79,347	$ 24,384

Research and development expenses were $103.7 million and $79.3 million for the years ended December 31, 2023 and 2022, respectively. The increase of approximately $24.4 million was primarily driven by an $11.2 million increase for our Phase 2 clinical-stage ADC programs which are being developed in multiple indications, a $7.4 million increase in our CTLA4 immuno-oncology program which progressed to Phase 2 development during 2023, a $4.8 million increase for various pre-clinical programs primarily our CAB B7-H3 x CD3 bispecific program and our next generation CAB Nectin-4 ADC program which we are advancing to IND, a $1.8 million increase in personnel related costs due to an increase in headcount to support ongoing development activities for our clinical programs, and a $1.2 million increase in facility and other allocated costs, offset by a decrease of $2.1 million related to our EpCAM bispecific program which completed manufacturing in 2022 and received an IND in February 2023.

General and administrative expense

General and administrative expenses were $26.0 million and $28.8 million for the years ended December 31, 2023 and 2022, respectively. The decrease of $2.8 million was primarily driven by a decrease of $1.1 million decrease in insurance due to a decrease in premiums for our D&O policy, a $1.1 million decrease in stock-based compensation related to awards issued under our 2020 Equity Incentive Plan, and a $0.7 million decrease in accounting, legal services and consulting primarily related to a $1.0 million legal settlement in 2022.

Interest income

Interest income was $6.3 million and $1.6 million for the years ended December 31, 2023 and 2022, respectively. The increase of $4.7 million was due to higher yields earned as compared to the same period in 2022.

Liquidity and capital resources

We have incurred aggregate net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. Since July 2020, we have funded our operations primarily through the issuance of equity. As of December 31, 2023, we had cash and cash equivalents of $111.5 million.

In January 2023, the Company entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") acting as sales agent pursuant to which the Company may, from time to time at its sole discretion, sell shares of the Company's common stock, with aggregate gross sales proceeds of up to $100.0 million. The Company will pay Jefferies a commission of 3.0% of the aggregate gross proceeds the Company receives from all sales of the Company's common stock under the Sales Agreement. We have not sold any shares of our common stock under the Sales Agreement as of December 31, 2023.

Future funding requirements

Our primary uses of cash are to fund operating expenses, which consist primarily of research and development expenses related to our programs and related personnel costs. The timing and amount of future funding requirements depends on many factors, including the following:

- the initiation, scope, rate of progress, results and costs of our preclinical studies, clinical trials and other related activities for our product candidates;
- the costs associated with manufacturing our product candidates and establishing commercial supplies and sales, marketing and distribution capabilities;
- the timing and costs of capital expenditures to support our research and development efforts;
- the number and characteristics of other product candidates that we pursue;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- the timing, receipt and amount of sales from our potential products;
- our need and ability to hire additional management, scientific and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the economic and other terms, timing and success of any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements;
- the compliance and administrative costs associated with being a public company; and
- the extent to which we acquire or invest in businesses, products or technologies, although we have no commitments or agreements relating to any of these types of transactions.

Based on our current operating plan, our current cash and cash equivalents are expected to be sufficient to fund our ongoing operations for a period of at least twelve months from the date the financial statements included in this report are issued. In addition, we have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

We will require additional funding in order to complete development of our product candidates and commercialize our products, if approved. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We cannot assure you that, in the event we require additional financing, such financing will be available at acceptable terms to us, if at all. Failure to generate sufficient cash flows from operations, raise additional capital, and reduce discretionary spending should additional capital not become available could have a material adverse effect on our ability to achieve our intended business objectives. 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 preclinical studies and clinical trials. To the extent that we raise additional capital through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product

candidates. We may also have to forego future revenue streams of research programs at an earlier stage of development or on less favorable terms than we would otherwise choose, or have to grant licenses on terms that may not be favorable to us. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. For example, market volatility resulting from a variety of causes, including supply chain disruptions, and geopolitical disruptions, including the recent conflict between Russia and Ukraine and the conflict between Israel and Hamas, could adversely impact our ability to access capital as and when needed. We may choose to raise additional capital through the issuance of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to our investors and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, acquiring other businesses, products or technology, or declaring dividends. If we are unable to obtain additional funding from these or other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delay, scale back or stop certain research and development programs.

Cash flows

The following summarizes our cash flows for the periods indicated:

	Years Ended December 31,	
	2023	2022
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (104,015)	$ (90,420)
Investing activities	(98)	(265)
Financing activities	77	61,213
Net decrease in cash and cash equivalents	$ (104,036)	$ (29,472)

Cash used in operating activities

Net cash used in operating activities for the year ended December 31, 2023 was $104.0 million, which consisted of a net loss of $123.5 million, a net change of $4.7 million in our net operating assets and liabilities and $14.8 million of non-cash transactions. The net change in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses of $5.3 million, partially offset by a decrease in operating lease right-of-use assets and liabilities of $0.6 million. The non-cash transactions primarily consisted of $13.5 million of stock-based compensation and non-cash charges of $1.2 million related to depreciation and amortization.

Net cash used in operating activities for the year ended December 31, 2022 was $90.4 million, which consisted of a net loss of $106.5 million, a net increase of $0.3 million in our net operating assets and liabilities and $15.8 million of non-cash transactions. The net change in our operating assets and liabilities was primarily due to an increase in prepaid expenses and other assets of $2.6 million, partially offset by an increase in accounts payable and accrued expenses of $3.4 million and a net decrease in operating lease right-of-use assets and liabilities of $0.5 million. The non-cash transactions primarily consisted of $14.6 million of stock-based compensation and non-cash charges of $1.2 million related to depreciation and amortization.

Cash used in investing activities

Cash used in investing activities was $0.1 million and $0.3 million for the years ended December 31, 2023 and 2022, respectively, primarily related to the purchase of property and equipment.

Cash provided by financing activities

Net cash provided by financing activities was $77,000 for the year ended December 31, 2023, which consisted primarily of the net proceeds from the issuance of common stock under our Employee Stock Purchase Plan of $336,000, partially offset by payment of taxes related to the net settlement of equity awards of $259,000.

Net cash provided by financing activities was $61.2 million for the year ended December 31, 2022, which consisted primarily of the $61.7 million net proceeds from the issuance of common stock through an underwritten offering in November 2022 and $0.3 million proceeds from the issuance of common stock under our Employee Stock Purchase Plan, partially offset by payment of taxes related to the net settlement of equity awards of $0.8 million.

Critical accounting policies and estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated, and reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions.

While our significant accounting policies are described in the Note 1 to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Accrued expenses

As part of the process of preparing our financial statements, we accrue expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. The estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Other company information

Recent Accounting Pronouncements

See Note 1 to the audited financial statements included in Item 8 of this Annual Report on Form 10-K.

Off-balance sheet arrangements

We have not entered into any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable to a smaller reporting company.

ITEM 8. Financial Statements and Supplementary Data

BioAtla, Inc.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of BioAtla, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of BioAtla, Inc. (the Company) as of December 31, 2023 and 2022, the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the 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 financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrual of Clinical Trial Expenses

Description of the Matter	During 2023, the Company incurred $103.7 million for research and development expenses and as of December 31, 2023 accrued $12.5 million for clinical trial costs. A substantial portion of the Company's ongoing research and development activities are conducted by third-party service providers, including clinical research organizations ("CROs"). External costs to be paid to CROs are accrued and expensed based upon actual work completed in accordance with signed agreements. Auditing management's accounting for accrued clinical trial costs is especially challenging because the evaluation is dependent upon a high-volume of data and input exchanged between clinical personnel and third-party service providers, such as the total trial management costs, number of sites activated, the number of patients enrolled, and the number of patient visits, which is tracked in spreadsheets and other end user computing programs.
How We Addressed the Matter in Our Audit	To test the completeness of the Company's accrued clinical trial expenses, we obtained from third-parties confirmation of the number of patients enrolled and costs billed but unpaid as of year-end for significant clinical trials. We obtained an understanding of the status of significant clinical trial activities from accounting personnel and the clinical project managers. To assess the appropriate measurement of accrued clinical trial expenses, we inspected key terms, timelines of completion, activities and costs for a sample of vendor contracts, including amendments, and compared these to management's analyses used in tracking the progress of service agreements. We also tested a sample of subsequent payments by agreeing the amount of the payment to the invoice and to the amount accrued.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2016.
San Diego, California
March 26, 2024

BioAtla, Inc.
Balance Sheets
(in thousands, except share amounts)

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 111,471	$ 215,507
Prepaid expenses and other current assets	4,935	4,924
Total current assets	116,406	220,431
Property and equipment, net	1,603	2,728
Operating lease right-of-use-asset, net	1,495	2,423
Other assets	154	154
Total assets	$ 119,658	$ 225,736
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 26,720	$ 21,610
Operating lease liabilities	1,624	1,521
Total current liabilities	28,344	23,131
Operating lease liabilities, less current portion	836	2,460
Liability to licensor	19,806	19,806
Total liabilities	48,986	45,397
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 200,000,000 shares authorized at December 31, 2023 and December 31, 2022; 0 shares issued and outstanding at December 31, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 350,000,000 shares authorized at December 31, 2023 and December 31, 2022; 48,077,599 and 46,336,166 shares issued and outstanding at December 31, 2023 and December 31, 2022	5	5
Class B common stock, $0.0001 par value; 15,368,569 shares authorized at December 31, 2023 and December 31, 2022; 0 and 1,211,959 shares issued and outstanding at December 31, 2023 and December 31, 2022	—	—
Additional paid-in capital	486,930	473,135
Accumulated deficit	(416,263)	(292,801)
Total stockholders' equity	70,672	180,339
Total liabilities and stockholders' equity	$ 119,658	$ 225,736

See accompanying notes.

BioAtla, Inc.
Statements of operations and comprehensive loss
(in thousands, except share and per share amounts)

	Years ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development expense	103,731	79,347
General and administrative expense	25,956	28,793
Total operating expenses	129,687	108,140
Loss from operations	(129,687)	(108,140)
Other income:		
Interest income	6,312	1,648
Other income (expense)	(87)	10
Total other income	6,225	1,658
Net loss and comprehensive loss	$ (123,462)	$ (106,482)
Net loss per common share, basic and diluted	$ (2.58)	$ (2.74)
Weighted-average shares of common stock outstanding, basic and diluted	47,777,568	38,927,268

See accompanying notes.

BioAtla, Inc.
Statements of stockholders' equity
(in thousands, except share amounts)

	Common stock		Class B common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	35,799,233	$ 4	1,492,059	$ —	$ 397,136	$ (186,319)	$ 210,821
Issuance of common stock, net of $3,318 of issuance costs	9,745,128	1	—	—	61,681	—	61,682
Issuance of common stock under equity incentive plans, net of shares withheld for taxes	364,141	—	—	—	—	—	—
Issuance of common stock for Employee Stock Purchase Plan	147,564	—	—	—	289	—	289
Taxes related to net share settlement of equity awards	—	—	—	—	(534)	—	(534)
Conversion of Class B Common Stock	280,100	—	(280,100)	—	—	—	—
Stock-based compensation expense	—	—	—	—	14,563	—	14,563
Net loss	—	—	—	—	—	(106,482)	(106,482)
Balance at December 31, 2022	46,336,166	$ 5	1,211,959	$ —	$ 473,135	$ (292,801)	$ 180,339
Issuance of common stock under equity incentive plans, net of shares withheld for taxes	318,634	—	—	—	—	—	—
Issuance of common stock for Employee Stock Purchase Plan	165,550	—	—	—	336	—	336
Issuance of common stock for director compensation	45,290	—	—	—	107	—	107
Taxes related to net share settlement of equity awards	—	—	—	—	(192)	—	(192)
Conversion of Class B Common Stock	1,211,959	—	(1,211,959)	—	—	—	—
Stock-based compensation expense	—	—	—	—	13,544	—	13,544
Net loss	—	—	—	—	—	(123,462)	(123,462)
Balance at December 31, 2023	48,077,599	$ 5	—	$ —	$ 486,930	$ (416,263)	$ 70,672

See accompanying notes.

BioAtla, Inc.
Statements of cash flows
(in thousands)

	Years ended December 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (123,462)	$ (106,482)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,221	1,199
Loss on disposal of property and equipment	2	13
Stock-based compensation	13,544	14,563
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(11)	(2,611)
Accounts payable and accrued expenses	5,284	3,411
Right-of-use assets and lease liabilities, net	(593)	(513)
Net cash used in operating activities	(104,015)	(90,420)
Cash flows from investing activities		
Purchases of property and equipment	(98)	(268)
Proceeds from sale of property and equipment	—	3
Net cash used in investing activities	(98)	(265)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	—	61,682
Proceeds from issuance of common stock under Employee Stock Purchase Plan	336	289
Payments for taxes related to net settlement of equity awards	(259)	(758)
Net cash provided by financing activities	77	61,213
Net decrease in cash and cash equivalents	(104,036)	(29,472)
Cash and cash equivalents, beginning of period	215,507	244,979
Cash and cash equivalents, end of period	$ 111,471	$ 215,507
Supplemental disclosure of non-cash investing and financing activities		
Property and equipment additions included in accounts payable and accrued expenses	$ —	$ 1
Tax related to net settlement of equity awards included in accounts payable and accrued expenses	$ 6	$ 67

See accompanying notes.

BioAtla, Inc.
Notes to financial statements

1. Organization and summary of significant accounting policies

Organization

BioAtla, LLC was formed in Delaware in March 2007 and was converted to a Delaware corporation in July 2020 and renamed BioAtla, Inc. (the "Company"). The Company has a proprietary platform for creating biologics, including its conditionally active biologics ("CAB" or "CABs"). CABs have been designed to be active only under certain conditions found in diseased tissue, while remaining inactive in normal tissue. The Company is currently in clinical development of its two lead CAB antibody drug conjugates ("CAB ADC") targeting AXL and ROR2 receptors, its CAB immune-oncology antibody targeting CTLA-4, and its CAB bispecific antibody targeting EpCAM.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). BioAtla, Inc. is a single legal entity with no consolidated variable interest entities ("VIEs") or subsidiaries (see Note 8).

Liquidity and Going Concern

The Company has incurred cumulative operating losses and negative cash flows from operations since its inception and expects to continue to incur significant expenses and operating losses for the foreseeable future as it continues the development of its product candidates. As of December 31, 2023, the Company had an accumulated deficit of $416.3 million. The Company plans to continue to fund its losses from operations and capital funding needs through public or private equity or debt financings, or other sources. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations and future prospects.

In January 2023, the Company entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC pursuant to which the Company may, from time to time at its sole discretion, sell shares of the Company's common stock, with aggregate gross sales proceeds of up to $100.0 million. The Company has not sold any shares of its common stock under the Sales Agreement as of December 31, 2023.

Management is required to perform a two-step analysis of the Company's ability to continue as a going concern. Management must first evaluate whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going concern (Step 1). If management concludes that substantial doubt is raised, management is also required to consider whether its plans alleviate that doubt (Step 2). Management's assessment included the preparation of cash flow forecasts resulting in management's conclusion that there is not substantial doubt about the Company's ability to continue as a going concern as its current cash and cash equivalents will be sufficient to fund the Company's operations for a period of at least one year from the issuance date of these financial statements.

Variable Interest Entities ("VIE")

The Company consolidates entities in which it has a controlling financial interest. The Company determines whether it has a controlling financial interest in an entity by first evaluating whether the entity is a voting interest entity or a VIE. VIEs are entities in which (i) the total equity investment at risk is sufficient to enable the entity to finance its activities independently, (ii) the equity holders have the power to direct the activities of the entity that most significantly impact its economic performance, the obligation to absorb the losses of the entity and the right to receive the residual returns of the entity and (iii) the legal entity is structured with substantive voting rights. A VIE is an entity that lacks one or more of the characteristics of a voting interest entity. The Company has a controlling financial interest in a VIE when the Company has a variable interest or interests that provide it with (i) the power to direct the activities of the VIE that most significantly impact the VIE's economic performance and (ii) the obligation to absorb losses of the VIE or the right to receive benefits from the VIE that could potentially be significant to the VIE. The Company evaluates its relationships with its VIEs on an ongoing basis to determine whether or not it has a controlling financial interest (see Note 8).

Use of Estimates

The Company's financial statements are prepared in accordance with U.S. GAAP. The preparation of the Company's financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to accruals for research and development costs, equity-based compensation and fair value measurements. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenue and expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash equivalents. Cash equivalents consist of highly rated securities including U.S. Government and U.S. Treasury money market funds, which are unrestricted as to withdrawal or use. The cash and cash equivalents balance as of December 31, 2023 and 2022 includes $50.4 million and $0, respectively, invested in U.S. Government and U.S. Treasury money market funds.

Concentrations of Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits and may invest cash that is not required for immediate operating needs in highly liquid instruments that bear minimal risk. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Property and Equipment

Property and equipment are stated at cost and depreciated on a straight-line basis over the estimated useful life of the related assets. Leasehold improvements are stated at cost and amortized on a straight-line basis over the lesser of the remaining term of the related lease or the estimated useful life of the leasehold improvements. Repairs and maintenance costs are charged to expense as incurred and expenditures that materially extend the useful lives of assets are capitalized.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, such as property and equipment, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Fair value would be assessed using discounted cash flows or other appropriate measures of fair value. The Company has not recognized any impairment losses for the years ended December 31, 2023 and 2022.

Leases

The Company determines if an arrangement is a lease at inception. An arrangement is or contains a lease if it conveys the right to control the use of an identified asset for a period of time in exchange for consideration. If a lease is identified, classification is determined at lease commencement. Operating lease liabilities are recognized at the present value of the future lease payments at the lease commencement date. The Company's leases do not provide an implicit interest rate and therefore the Company estimates its incremental borrowing rate to discount lease payments. The incremental borrowing rate reflects the interest rate that the Company would have to pay to borrow on a collateralized basis an amount equal to the lease payments in a similar economic environment over a similar term. Operating lease right-of-use ("ROU") assets are based on the corresponding lease liability adjusted for any lease payments made at or before commencement, initial direct costs, and lease incentives. Renewals or early terminations are not accounted for unless the Company is reasonably certain to exercise these options. Operating lease expense is recognized and the ROU asset is amortized on a straight-line basis over the lease term. Variable lease costs are not included in the calculation of the ROU asset and the related lease liability and are recognized as incurred.

The Company has a single lease agreement with lease and non-lease components, which are accounted for as a single lease component. Payments for short-term leases, defined as leases with a term of twelve months or less, are expensed on a straight-line basis over the lease term. The Company does not currently have any short-term leases.

Operating leases are included in operating lease right-of-use assets, operating lease liabilities, and operating lease liabilities, non-current on the Company's balance sheets. The Company does not have any finance leases.

Revenue Recognition

The Company recognizes revenue in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration the Company is entitled to receive in exchange for such product or service. In doing so, the Company follows a five-step approach: (i) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue when (or as) the customer obtains control of the product or service. The Company considers the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard.

A customer is a party that has entered into a contract with the Company, where the purpose of the contract is to obtain a product or a service that is an output of the Company's ordinary activities in exchange for consideration. To be considered a contract, (i) the contract must be approved (in writing, orally, or in accordance with other customary business practices), (ii) each party's rights regarding the product or the service to be transferred can be identified, (iii) the payment terms for the product or the service to be transferred can be identified, (iv) the contract must have commercial substance (that is, the risk, timing or amount of future cash flows is expected to change as a result of the contract), and (v) it is probable that the Company will collect substantially all of the consideration to which it is entitled to receive in exchange for the transfer of the product or the service.

A performance obligation is defined as a promise to transfer a product or a service to a customer. The Company identifies each promise to transfer a product or a service (or a bundle of products or services, or a series of products and services that are substantially the same and have the same pattern of transfer) that is distinct. A product or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) the Company's promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not separately identifiable from other promises in the contract, such promises should be combined into a single performance obligation.

The transaction price is the amount of consideration the Company is entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, the Company considers the existence of any significant financing component, the effects of any variable elements, noncash consideration and consideration payable to the customer. If a significant financing component exists, the transaction price is adjusted for the time value of money. If an element of variability exists, the Company must estimate the consideration it expects to receive and uses that amount as the basis for recognizing revenue as the product or the service is transferred to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts.

If a contract has multiple performance obligations, the Company allocates the transaction price to each distinct performance obligation in an amount that reflects the consideration the Company is entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when the Company transfers control of the product or the service applicable to such performance obligation.

In those instances where the Company first receives consideration in advance of satisfying its performance obligation, the Company classifies such consideration as deferred revenue until (or as) the Company satisfies such performance obligation. In those instances where the Company first satisfies its performance obligation prior to its receipt of consideration, the consideration is recorded as accounts receivable.

The Company expenses incremental costs of obtaining and fulfilling a contract as incurred if the expected amortization period of the asset that would be recognized is one year or less, or if the amount of the asset is immaterial. Otherwise, such costs are capitalized as contract assets if they are incremental to the contract and amortized to expense proportionate to revenue recognition of the underlying contract.

Research and Development Expenses

The Company's activities have largely consisted of research and development efforts related to developing our CAB programs. Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and other outside expenses. Research and development expenses are charged to expense as incurred. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in the accompanying balance sheets as prepaid or accrued expenses. When evaluating the adequacy of the accrued expenses, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

As of December 31, 2023, the Company has accrued $12.5 million related to clinical trial costs. The Company has entered into contracts related to its clinical trials with clinical research organizations. The Company reviews and accrues clinical trial costs based on work performed, which relies on estimates and assumptions of total trial management costs, sites activated, patients enrolled, and number of patient visits. The Company follows this method since reasonably dependable estimates of the costs applicable to clinical trials can be made. Accrued clinical trial costs are subject to revisions as the trials progress. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. A modification in the protocol of a clinical trial or cancellation of a trial could result in a material change to the Company's results of operations.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expenses and expensed as incurred since recoverability of such expenditures is uncertain.

Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of equity awards, consisting of stock options, restricted stock units ("RSUs") and employee stock purchase plan rights, over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The Company estimates the fair value of stock option grants and employee stock purchase plan rights using the Black-Scholes option pricing model. Prior to the Company's IPO, the fair value of RSUs was based on the estimated fair value of the underlying common stock on the date of grant and, subsequent to the Company's IPO, the fair value is based on the closing sales price of the Company's common stock on the date of grant. Equity award forfeitures are recognized as they occur.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax basis of assets and liabilities using enacted

tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized as income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, exclusive of reversing temporary difference, tax-planning strategies, and the results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. There have been no items qualifying as other comprehensive loss and, therefore, for all periods presented, the Company's comprehensive loss was the same as its reported net loss.

Net Loss Per Share

Basic net loss per common share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of RSUs, common stock options outstanding under the Company's stock option plan, and contingently issuable shares under the BioAtla, Inc. Employee Stock Purchase Plan (the "ESPP").

Potentially dilutive securities not included in the calculation of diluted net loss per common share because to do so would be anti-dilutive are as follows (in common stock equivalents):

	December 31,	
	2023	2022
Common stock options	6,273,507	2,736,918
Restricted stock units	99,104	510,039
ESPP Shares	57,253	13,370
Total	6,429,864	3,260,327

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures". ASU 2023-09 requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its financial statements.

2. Balance sheet details

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,	
	2023	2022
Prepaid research and development	$ 4,615	$ 4,385
Other prepaid expenses and current assets	320	539
Total	$ 4,935	$ 4,924

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

	Useful life (years)	December 31, 2023	December 31, 2022
Furniture, fixtures and office equipment	3 - 7	$ 1,721	$ 2,140
Laboratory equipment	5	2,280	2,265
Leasehold improvements	2 - 3	3,680	3,687
		7,681	8,092
Less accumulated depreciation and amortization		(6,078)	(5,364)
Total		$ 1,603	$ 2,728

Accounts payable and accrued expenses consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Accounts payable	$ 3,819	$ 4,231
Accrued compensation	3,790	3,451
Accrued research and development	18,246	12,649
Other accrued expenses	865	1,279
Total	$ 26,720	$ 21,610

3. Fair value measurements

The carrying amounts of the Company's current financial assets and current financial liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. As of December 31, 2023 and December 31, 2022, the Company had no financial assets or liabilities measured at fair value on a recurring basis.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

As of December 31, 2023 and 2022, the Company had $50.4 million and $0, respectively, invested in U.S. Government and U.S. Treasury money market funds which are recorded as cash equivalents and represent a Level 1 measurement within the fair value hierarchy.

None of the Company's non-financial assets and liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

4. Leases

The Company has a single operating lease for its corporate headquarters and laboratory space in San Diego, California. The lease expires in July 2025 and the Company has an option to extend the term of the lease for an additional five years. Additionally, the lease includes certain rent abatement, rent escalations, tenant improvement allowances and additional charges for common area maintenance and other costs.

The components of lease expense included in the Company's statements of operations and loss include (in thousands):

	Years ended December 31,	
	2023	2022
Operating lease expense	$ 1,043	$ 1,043
Variable lease expense	544	460
Total lease expense, net	$ 1,587	$ 1,503

Variable lease costs are primarily related to payments made to lessors for common area maintenance, property taxes, insurance, and other operating expenses. The Company did not have any short-term leases or finance leases for the year ended December 31, 2023.

The weighted average remaining lease term and weighted average discount rate for operating leases were as follows:

	December 31,	
	2023	2022
Weighted average remaining lease term (in years)	1.5	2.5
Weighted average discount rate percentage	3.50%	3.50%

Supplemental cash flow information related to leases under which the Company is the lessee was as follows (amounts in thousands):

	Years ended December 31,	
	2023	2022
Cash paid for amounts included in the measurement of operating leases	$ 1,500	$ 1,555

Maturities of operating lease liabilities as of December 31, 2023 were as follows (in thousands):

Years ending December 31:	Operating lease
2024	$ 1,685
2025	845
Thereafter	—
Total future lease payments	2,530
Less imputed interest	(70)
Total operating lease liabilities	$ 2,460

5. Commitments and contingencies

From time to time, the Company may be subject to various claims and suits arising in the ordinary course of business. The Company is not currently a party to any legal proceedings the outcome of which the Company believes, if determined adversely to the Company, would individually or in the aggregate have a material adverse effect on the Company's business, operating results or financial condition.

6. Stockholders' equity

Description of securities of Delaware corporation

The Company is authorized to issue 200,000,000 shares of preferred stock, par value $0.0001 per share, 350,000,000 shares of common stock, par value $0.0001 per share, and 15,368,569 shares of Class B common stock, par value $0.0001 per share.

Dividends

Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of the Company's common stock and Class B common stock are entitled to receive dividends only if declared from time to time by the Company's board of directors out of assets which are legally available.

Liquidation preferences

Upon any liquidation, dissolution or winding-up of the Company, holders of the Company's common stock and Class B common stock are entitled to share ratably in all assets remaining after payment of all liabilities and the liquidation preferences of any of our outstanding shares of preferred stock.

Conversion

Holders of the Company's common stock have no conversion rights, while holders of the Company's Class B common stock shall have the right to convert each share of Class B common stock into one share of common stock at such holder's election, provided that as a result of such conversion, such holder would not beneficially own in excess of 4.99% of any class of the Company's securities registered under the Securities Exchange Act of 1934, as amended, unless otherwise as expressly provided for in the Company's amended and restated certificate of incorporation. This ownership limitation may be increased or decreased to any other percentage designated by such holder of Class B common stock upon 61 days' notice to the Company.

Voting rights

Except as otherwise expressly provided in the Company's amended and restated certificate of incorporation or as required by applicable law, on any matter that is submitted to a vote by the Company's stockholders, holders of the Company's common stock are entitled to one vote per share of common stock, and holders of the Company's Class B common stock are not entitled to any votes per share of Class B common stock, including for the election of directors.

November 2022 Underwritten Offering

On November 8, 2022, the Company completed a follow-on offering under its shelf registration statement on Form S-3 (File No. 333-262528) and a related prospectus supplement pursuant to which the Company issued an aggregate of 9,745,128 shares of its common stock to at a public offering price of $6.67 per share. The Company received aggregate net proceeds of $61.7 million from the offering after deducting underwriting discounts and commissions and other offering expenses.

Common stock warrants

The Company issued the warrants described below in 2016 in connection with certain advisory services. The warrants became exercisable upon the Company's IPO for a period of 365 and 450 days.

Upon adoption of ASU No. 2018-07 on October 1, 2020, the measurement date of the warrants became fixed in accordance with the guidance, and such fair value was nominal since the warrants were deeply out-of-the-money. In December 2021, a total of 566,586 warrants with an exercise period of 365 days after the Company's IPO expired unexercised. The remaining 151,088 warrants with an exercise period of 450 days after the Company's IPO expired unexercised in March 2022. Accordingly, there are no remaining common stock warrants outstanding and exercisable at December 31, 2022 or December 31, 2023.

Open market sale agreement

In January 2023, BioAtla, Inc. (the "Company") entered into an open market sale agreement under which the Company may offer and sell, from time to time in its sole discretion, shares of the Company's common stock, par value $0.0001 per share, with aggregate gross sales proceeds of up to $100,000,000 through an "at the market" equity offering program under which Jefferies LLC will act as sales agent. No shares have been sold under the agreement to date.

2020 Equity Incentive Plan

On October 29, 2020, the Company's board of directors approved the adoption of the BioAtla, Inc. 2020 Equity Incentive Plan (the "2020 Plan") and approved certain amendments to the 2020 Plan in December 2020. The Company's stockholders approved the 2020 Plan, as amended, in December 2020. Under the 2020 Plan, the Company may grant awards of common stock to the Company's employees, consultants and non-employee directors pursuant to option awards, stock appreciation rights awards, restricted stock awards, restricted stock unit awards, performance stock awards, performance stock unit awards and other stock-based awards. As of December 31, 2023 and 2022, the total number of common shares authorized for issuance under the 2020 Plan was 9,196,970 and 7,658,509, respectively. On January 1st of each year, commencing with the first January 1st following the effective date of the 2020 Plan, the shares authorized for issuance under the 2020 Plan shall be increased by a number of shares equal to the lesser of 4% of the total number of shares outstanding on the immediately preceding December 31st and such lesser number of shares determined by the Company's board of directors. The maximum term of the options granted under the 2020 Plan is no more than ten years. Awards under the 2020 Plan generally vest at 25% one year from the vesting commencement date and ratably each month thereafter for a period of 36 months, subject to continuous service.

On February 26, 2023, the Compensation Committee of the Company's board of directors approved a modification to the Company's 2020 Plan to allow vesting of RSUs or stock options, as applicable, subject to the grantee's continued service to the Company and/or one of its subsidiaries as an employee, non-employee director, or independent contractor. Unvested RSUs totaling 139,730 shares and 574,244 unvested options which would have been forfeited under the original terms of the 2020 Plan will now continue to vest. The Company applied modification accounting to these awards which resulted in a decrease in fair value to these awards. The Company calculated compensation cost for the modified unvested awards of $416,000 related to the RSUs and $962,000 related to the options, and will recognize these amounts over the remaining requisite service periods. The modification also resulted in an increase to the term of 130,699 fully vested options for which $123,000 of incremental compensation cost was immediately recognized on the date of the modification.

Stock-based compensation expense recognized for all equity awards under the 2020 Plan has been reported in the statements of operations and comprehensive loss as follows (in thousands):

	Years ended December 31,	
	2023	2022
Research and development	$ 5,462	$ 5,419
General and administrative	8,082	9,144
Total	$ 13,544	$ 14,563

Restricted stock units

In December 2022, the Company's board of directors approved an amendment to the Director Compensation Policy, which allows each director to elect to receive their quarterly director fees in the form of restricted stock in lieu of cash. Two board members elected to receive shares of restricted stock in lieu of cash. For the twelve months ended December 31, 2023, the Company issued 45,290 shares of fully vested restricted stock to the two board members. Compensation expense was earned and recognized for these fully vested restricted stock grants in the amount of $0.1 million for the twelve months ended December 31, 2023.

The following table summarizes RSU activity under the 2020 Plan for the years ended December 31, 2023 and 2022:

	Number of Shares	Weighted - average grant date fair value
Outstanding at December 31, 2021	975,046	$ —
Granted	—	$ —
Vested	(446,260)	$ 18.00
Forfeited	(18,747)	
Outstanding at December 31, 2022	510,039	$ 18.00
Granted	45,290	$ 2.35
Vested	(433,948)	$ 16.37
Forfeited	(22,277)	$ 18.00
Outstanding at December 31, 2023	99,104	$ 18.00

As of December 31, 2023, total unrecognized stock-based compensation expense for RSUs was $1.8 million, which is expected to be recognized over a remaining weighted-average period of approximately 0.7 years.

Stock options

The following table summarizes stock option activity under the 2020 Plan for the year ended December 31, 2023 and 2022 (in thousands, except share and per option data and years):

	Number of options	Weighted - average exercise price per option	Weighted - average remaining contractual term (in years)	Aggregate intrinsic value
Balance at December 31, 2021	1,086,902	$ 26.76	9.22	$ 991,495
Granted	1,718,200	$ 6.35		
Exercised	—	$ —		
Forfeited	(50,387)	$ 21.64		
Expired	(17,797)	$ 40.00		
Balance at December 31, 2022	2,736,918	$ 13.82	8.82	$ 3,636,148
Granted	4,020,395	$ 3.74		
Exercised	—	$ —		
Forfeited	(371,439)	$ 7.20		
Expired	(112,367)	$ 20.96		
Balance at December 31, 2023	6,273,507	$ 7.62	8.64	$ 74,680
Vested and expected to vest at December 31, 2023	6,273,507	$ 7.62	8.64	$ 74,680
Exercisable at December 31, 2023	1,429,449	$ 14.98	7.75	$ 2,007

As of December 31, 2023, total unrecognized stock-based compensation cost for unvested common stock options was $15.6 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.8 years. The weighted- average grant date fair value of stock options granted during the years ended December 31, 2023 and 2022 was $2.61 per share and $4.06 per share, respectively. The total fair value of options vested during the years ended December 31, 2023 and 2022 was $6.7 million and $6.9 million, respectively. Upon option exercise, the Company issues new shares of its common stock.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of stock option grants were as follows:

	Years ended December 31,	
	2023	2022
Expected volatility	77.9%	74.9%
Risk-free interest rate	3.89%	2.14%
Expected dividend yield	0.0%	0.0%
Expected term	6.05 years	6.04 years

Expected volatility. As the Company's common stock does not have a significant trading history, the expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry.

Risk-free interest rate. The Company bases the risk-free interest rate assumption on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present plans to pay cash dividends.

Expected term. For employees, the expected term represents the period of time that options are expected to be outstanding. Because the Company has minimal historical exercise behavior, it determines the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period. For nonemployees, the expected term is generally the contractual term of the option.

Employee Stock Purchase Plan

In December 2020, the Company's board of directors and stockholders approved the BioAtla, Inc. Employee Stock Purchase Plan (the "ESPP"). The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. As of December 31, 2023 and 2022, a total of 1,737,098 and 1,229,148 shares, respectively, of common stock were authorized for issuance under the ESPP. The number of shares of common stock authorized for issuance will automatically increase on January 1 of each calendar year, from January 1, 2021 through January 1, 2030 by the least of (i) 1.0% of the total number of common shares of our common stock outstanding on December 31 of the preceding calendar year (calculated on a fully diluted basis), (ii) 929,658 common shares or (iii) a number determined by the Company's board of directors that is less than (i) and (ii). During the years ended December 31, 2023 and 2022, the Company issued 165,550 and 147,564 shares of common stock under the ESPP, respectively. As of December 31, 2023, 1,412,802 shares of common stock remained available for issuance under the ESPP. Stock-based compensation expense related to the ESPP for the twelve months ended December 31, 2023 and 2022 was $0.2 million, respectively.

Common stock reserved for future issuance

Common stock reserved for future issuance are as follows in common equivalent shares:

	December 31,	
	2023	2022
Common stock options and restricted stock units issued and outstanding	6,372,611	3,246,957
Awards available for future issuance under the 2020 Plan	991,413	3,012,554
Awards available for future issuance under the ESPP	1,412,802	1,070,402
Total common stock reserved for future issuance	8,776,826	7,329,913

7. Collaboration, license and option agreements

Global Co-Development and Collaboration Agreement with BeiGene

In April 2019, the Company entered into a Global Co-Development and Collaboration agreement (the "BeiGene Collaboration") with BeiGene, Ltd. and BeiGene Switzerland GmbH (collectively "BeiGene"), for the development, manufacturing and commercialization of the Company's investigational CAB CTLA-4 antibody (evalstotug, BA3071). The BeiGene Collaboration was amended several times between 2019 and 2021 and the Company received a total of $25.0 million in non-refundable payments from BeiGene during that time.

In November 2021, the BeiGene Collaboration was terminated, subject to survival of certain provisions, and BeiGene handed back rights to know-how and materials received under the amended BeiGene Collaboration. As a result, the Company is responsible for the global development and commercialization of evalstotug. As consideration for this amendment, the Company agreed to pay BeiGene mid-single digit royalties on sales worldwide and on a limited basis will share in any upfront and milestone payments received through a sublicense of evalstotug. The Company reclassified its then remaining $19.8 million of deferred revenue as a long-term liability which is expected to settle as licensing payments are made to BeiGene in accordance with the resulting amendment. In the event the license is terminated, the liability will be extinguished with no further payment to BeiGene.

The Company did not recognize any revenue related to the collaboration agreement with BeiGene for the years ended December 31, 2023 and 2022. The Company had a $19.8 million Liability to Licensor as of December 31, 2023 and 2022.

Collaboration and Supply Agreement with Bristol-Myers Squib

In January 2022, the Company and Bristol-Myers Squibb Company ("BMS") entered into a clinical trial collaboration and supply agreement (the "BMS Agreement"). Under the terms of the BMS Agreement, BioAtla and BMS will collaborate on clinical trials of separate combination therapies using two of BioAtla's Conditionally Active Biologic Antibody Drug Conjugates, mecbotamab vedotin (BA3011) and ozuriftamab vedotin (BA3021), each in combination with Opdivo® (nivolumab), BMS' proprietary anti-PD-1 monoclonal antibody product. The Company will serve as the study sponsor of the scheduled studies and will be responsible for costs associated with the trial execution. BMS will provide Opdivo® clinical drug supply at no cost for the combination study trials. After the completion of the combination therapy trials, the Company is obligated to provide BMS with a final report of the data resulting from the trial. The BMS Agreement was amended in October 2022 to include additional territories for our mecbotamab vedotin and ozuriftamab vedotin combination study trials. There was no impact to the Company's financial results for the years ended December 31, 2023 or 2022 as a result of this agreement.

8. Related party transactions

Inversagen, LLC

On March 15, 2019, the Company entered into an Exclusive License Agreement with Inversagen (the "Inversagen License"). Under the terms of the agreement, Inversagen acquired the rights to CAB-antibodies for the field of diseases associated with aging, outside of cancer, and an immuno-oncology antibody. The Company may perform development services under the agreement and will be reimbursed by Inversagen for its costs. Commencing on the first commercial sale of the CAB-antibodies and immuno-oncology antibody subject to the Inversagen License, Inversagen will pay the Company milestone payments and royalties, which represent a variable interest held by the Company. On July 7, 2020, the Company and Inversagen entered into the First Amendment to Exclusive License Agreement ("Amended Inversagen License"), which grants the Company an option for a period of 10 years to acquire the immuno-oncology antibody in return for royalty payments in the low-single digits during the applicable royalty term. No payments have been made to date.

Inversagen has only nominal assets and liabilities and is a VIE as the entity lacks sufficient equity to finance its activities without additional subordinated financial support. The Company does not consolidate Inversagen as it is not the primary beneficiary; the Inversagen License and the Amended Inversagen License did not and do not provide the Company with any decision-making power over the activities that are most significant to the entity's economic success, such as the direction of its development efforts or the search for or terms of any future financing arrangements. The Company has no equity interest in Inversagen, and no exposure to its losses. The Company has not provided any services to Inversagen, has not provided any support to Inversagen and has no obligation to do so, and Inversagen's creditors have no recourse to the general credit of the Company. The Company does not have any assets or liabilities associated with its variable interest in Inversagen at December 31, 2023 and 2022.

Inversagen is a related party of the Company. Dr. Jay Short and his spouse serve as managers of Inversagen.

BioAtla Holdings, LLC

Effective January 1, 2020, the Company entered into an Exclusive License Agreement (the "BioAtla Holdings License") with BioAtla Holdings, LLC. Under the terms of the agreement, BioAtla Holdings acquired the rights to CAB antibodies for certain targets in the field of Adoptive Cell Therapy (CAR-T format) in exchange for potential royalty payments on future net sales. On July 7, 2020, the Company and BioAtla Holdings entered into the First Amendment to Exclusive License Agreement (the "Amended BioAtla Holdings License"), which grants the Company an option for a period of 10 years to acquire the ACT Preparations and ACT Treatments in return for royalty payments in the low-single digits during the applicable royalty term. The Company has not exercised its option and no payments have been made to date under these agreements.

In addition, effective January 1, 2020, the Company entered into a Royalty Sharing Agreement whereby the Company agreed to share with BioAtla Holdings 50% of the royalties it receives from its Exclusive License Agreement with EXUMA Biotech Corp.

BioAtla Holdings is a variable interest entity as it does not have sufficient equity to finance its activities without additional subordinated financial support. The royalty payments and option to acquire assets represent variable interests held by the Company in BioAtla Holdings. The Company is not the primary beneficiary of BioAtla Holdings, however, as the BioAtla Holdings License and Amended BioAtla Holdings License did not and do not provide the Company with any decision-making power over the activities that are most significant to the entity's economic success, such as the direction of its development efforts or the search for or terms of any future financing arrangements. The Company has no equity interest in BioAtla Holdings, and no exposure to its losses. BioAtla Holdings is currently inactive, and the Company has not provided any support to BioAtla Holdings and has no obligation to do so, and BioAtla Holdings' creditors have no recourse to the general credit of the Company. The Company does not have any assets or liabilities associated with its variable interests in BioAtla Holdings at December 31, 2023 and 2022.

BioAtla Holdings is a related party of the Company. Dr. Jay Short and his spouse serve as managers of BioAtla Holdings.

Himalaya Therapeutics SEZC

Exclusive Rights Agreement

On January 1, 2020, the Company entered into an Amended and Restated Exclusive Rights Agreement (the "Amended Rights Agreement") with Himalaya Therapeutics SEZC. Under the terms of the Amended Rights Agreement, Himalaya Therapeutics SEZC acquired the rights to 10 CAB-antibodies for the territory of China, Macao, Hong Kong and Taiwan, global rights to a CAB-HER2-bispecific-antibody and global co-development rights with the Company to an IL-22 non-CAB-antibody. Payments to the Company may include upfront payments, milestone payments and double digit royalties, which represent a variable interest held by the Company, but no payments have been made to the Company to date.

Himalaya Therapeutics SEZC is a VIE as it does not have sufficient equity to finance its activities without additional subordinated financial support. The Company is not obligated to provide financial support to Himalaya Therapeutics SEZC. The Company is not the primary beneficiary of Himalaya Therapeutics SEZC, however, as the Amended Rights Agreement does not provide BioAtla, Inc. with the power to direct activities of a VIE that most significantly impact the VIE's economic performance, such as decision-making power over the direction of its development efforts or the search for or terms of any future financing arrangements. The Company does not have any assets or liabilities recorded at December 31, 2023 associated with its variable interest in Himalaya Therapeutics SEZC, and has no exposure to Himalaya Therapeutics SEZC losses.

Himalaya Therapeutics SEZC is a related party as Dr. Jay Short and his spouse serve as directors, and Dr. Short's spouse also serves as an officer of such entity.

Clinical Trial Services Agreement

In April 2022, the Company entered into a Clinical Trial Agreement with Himalaya Therapeutics SEZC. Under the agreement, Himalaya Therapeutics SEZC agreed to provide services related to the initiation of clinical trials for mecbotamab vedotin in the People's Republic of China. For the first year following effectiveness of the agreement, the Company has agreed to pay Himalaya Therapeutics SEZC for the full-time use of two of its personnel. Payments were due and payable by BioAtla to Himalaya Therapeutics SEZC on a quarterly calendar basis and are non-refundable. The Company made its final payment under the agreement in January 2023. For the twelve months ended December 31, 2023 and 2022, the Company recognized $0.1 million and $0.4 million in research and development expense related to the Clinical Trial Agreement, respectively. The Company did not have any amounts due from or due to Himalaya Therapeutics SEZC as of December 31, 2023. In January 2024, the Clinical Trial Agreement was amended to extend the agreement for 12 additional months. Under the amended agreement, BioAtla will pay Himalaya Therapeutics SEZC for the full-time use of two of its personnel and provide services related to the initiation of clinical trials for evalstotug in China.

Himalaya Parent LLC

Dr. Jay Short and his spouse serve as managers of Himalaya Parent LLC. The Company does not have a variable interest in Himalaya Parent LLC.

November 2022 Underwritten Offering

As part of the 2022 underwritten offering, the Company issued 2,998,500 shares of common stock for total net proceeds of $19.1 million to certain stockholders considered to be related parties.

9. 401(k) plan

The Company maintains a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. The Company, at its discretion, may make certain matching contributions to the 401(k) plan. To date, the Company has not made any matching contributions.

10. Income taxes

A reconciliation of income tax expense computed at the U.S. federal statutory income tax rate to the Company's income tax expense is as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Tax computed at the federal statutory rate	$ (25,927)	$ (22,361)
State income taxes, net of federal tax benefit	(8)	(6)
Nondeductible executive compensation	99	685
Stock-based compensation	1,326	1,132
Research and development and orphan drug credits	(6,205)	(3,692)
Uncertain tax positions	1,551	910
Other, net	228	(23)
Valuation allowance	28,936	23,355
Income tax expense	$ —	$ —

The Company's net deferred tax assets (liabilities) are as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 25,034	$ 17,430
Liability to licensor	4,159	4,159
Goodwill	2,938	3,193
Lease liability	517	836
Accrued compensation	746	659
Research credit carryforwards	10,379	5,760
Section 174 cost capitalization	31,220	14,523
Section 59(e) cost capitalization	8,400	9,450
Stock-based compensation	2,790	1,628
Other	4	3
Gross deferred tax assets	86,187	57,641
Less: valuation allowance	(85,642)	(56,706)
Total deferred tax assets	545	935
Deferred tax liabilities:		
Fixed assets	(231)	(426)
Operating lease right-of-use asset	(314)	(509)
Total deferred tax liabilities	(545)	(935)
Net deferred tax assets	$ —	$ —

A valuation allowance of approximately $85.6 million as of December 31, 2023 has been established to offset the deferred tax assets as the Company has determined that it is not more likely than not that these assets will be realized. The valuation allowance increased by approximately $28.9 million during 2023.

At December 31, 2023, the Company had federal and state net operating loss carryforwards of approximately $119.2 million and $0.2 million, respectively. The federal and state net operating losses can be carried forward indefinitely, subject to an 80% limitation against taxable income. The state net operating losses will begin to expire in 2042, unless previously utilized.

At December 31, 2023, the Company had federal and California research and development credit carryforwards of approximately $7.8 million and $2.7 million, respectively. The federal credit carryforwards will begin to expire in 2040, unless previously utilized. The California credits will carry forward indefinitely.

At December 31, 2023, the Company also had federal orphan drug credit carryforwards of approximately $3.9 million. The orphan drug credit carryforwards will begin to expire in 2041, unless previously utilized.

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of remaining tax attribute carryforwards available to offset future taxable income and income tax expense in future years may be significantly restricted or eliminated. Further, the Company's deferred tax assets associated with such tax attributes could be significantly reduced upon realization of an ownership change within the meaning of IRC Section 382.

Under the FASB's accounting guidance related to income tax positions, among other things, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, the guidance provides further clarification on derecognition, classification, interest and penalties, accounting in interim period, disclosure and transition. The Company regularly evaluates the likelihood of recognizing the benefit for income tax positions taken in various federal and state filings by considering all relevant facts, circumstances, and information available.

A reconciliation of the beginning and ending unrecognized tax benefit amount is as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Unrecognized tax benefits - beginning	$ 1,968	$ 1,011
Gross increases - tax positions in prior period	161	11
Gross increase – current-period tax positions	1,473	946
Unrecognized tax benefits - ending	$ 3,602	$ 1,968

As of December 31, 2023, the Company had gross unrecognized tax benefits of approximately $3.6 million, none of which would affect the Company's effective tax rate due to the existence of the valuation allowance. The Company's policy is to recognize interest and penalties related

to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company's balance sheet and has not recognized interest or penalties in the statements of operations and comprehensive income for the year ended December 31, 2023. The Company does not anticipate a significant change to its liability for unrecognized tax benefits within the next twelve months.

The Company is subject to taxation in the United States and various state jurisdictions. The Company is subject to examination by tax authorities in those jurisdictions since 2020 and 2019, respectively, and forward. However, to the extent allowed by law, the taxing authorities may have the right to examine periods where NOLs and research and development credits were generated and carried forward, and make adjustments to the amount of the NOL and research credits carryforward amount. The Company is not currently under examination by any jurisdiction.

11. Subsequent events

The Company has completed an evaluation of all subsequent events through March 26, 2024 for the financial statements as of and for the year ended December 31, 2023 to ensure these financial statements include appropriate disclosure of events both recognized in the financial statements and events which occurred but were not recognized in the financial statements. Except as described below or elsewhere in these financial statements, the Company has concluded that no subsequent event has occurred that requires disclosure.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures" as defined 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 ensure 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 SEC's rules and forms. 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 officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on the assessment, management has concluded that its internal control over financial reporting was effective as of December 31, 2023, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP.

Changes in Internal Control over Financial Reporting.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) that occurred during our most recently completed fiscal quarter. Based on that evaluation, our principal executive officers and principal financial officer concluded that there has not been any material change in our internal control over financial reporting during the fourth quarter of fiscal 2023 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures and Internal Control over Financial Reporting

In designing and evaluating the disclosure controls and procedures and internal control over financial reporting, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures and internal control over financial reporting must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

See Management's Report on Internal Control over Financial Reporting above.

ITEM 9B. Other Information

During the fiscal quarter ended December 31, 2023, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

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 Proxy Statement to be filed with the SEC and is incorporated herein by reference.

We have adopted a Company Code of Business Conduct and Ethics that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. A current copy of the Code of Business Conduct and Ethics is available on the Corporate Governance section of our website at www.bioatla.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K.

ITEM 11. Executive Compensation

The information required by this Item 11 will be included in our Proxy Statement to be filed with the SEC 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 Proxy Statement to be filed with the SEC and is incorporated herein by reference.

ITEM 13. Certain Relationships and Related Party Transactions, and Director Independence

The information required by this Item 13 will be included in our Proxy Statement to be filed with the SEC 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 Proxy Statement to be filed with the SEC and is incorporated herein by reference.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules

(a) Documents files as part of this Annual Report on Form 10-K:

(1) Financial Statements

The response to this portion of Item 15 is set forth under Item 8 hereof.

(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not applicable, not required, or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The exhibits listed in the Exhibit Index are incorporated by reference herein.

ITEM 16. Form 10-K Summary

None.

Exhibit Index

The following exhibits, if not filed or furnished herewith, are incorporated herein by reference to this Annual Report on form 10-K:

Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Exhibit Filing Date	Filed/Furnished Herewith
3.1	Amended and Restated Certificate of Incorporation of BioAtla, Inc.	8-K	001-39787	3.1	12-18-2020	
3.2	Amended and Restated Bylaws of BioAtla, Inc.	8-K	001-39787	3.1	01-05-2024	
4.1	Specimen Common Stock Certificate evidencing the shares of common stock	S-1/A	333-250093	4.1	12-08-2020	
4.2	Investors' Rights Agreement, dated July 13, 2020	S-1/A	333-250093	4.2	12-08-2020	
4.3	Description of Securities					X
10.1+	2020 Equity Incentive Plan	S-1/A	333-250093	10.1	12-08-2020	
10.2+	Amendment No. 1 to 2020 Equity Incentive Plan	S-8	333-251520	99.2	12-18-2020	
10.3+	2020 Employee Stock Purchase Plan	S-1/A	333-250093	10.3	12-08-2020	
10.4*	Exclusive Rights Agreement with Himalaya SEZC, dated January 1, 2020	S-1	333-250093	10.4	11-13-2020	
10.5*	Global Co-Development and Collaboration Agreement with BeiGene, Ltd. and BeiGene Switzerland GmbH, dated April 8, 2019, as amended by First Amendment, dated December 24, 2019 and as amended by Second Amendment, October 5, 2020	S-1	333-250093	10.8	11-13-2020	
10.6+	Employment Letter Agreement between BioAtla, LLC and Jay Short, as amended by the Letter Amendment dated October 1, 2011	S-1/A	333-250093	10.11	12-08-2020	
10.7+	Severance Agreement between BioAtla, LLC and Jay Short, dated July 1, 2018	S-1/A	333-250093	10.13	12-08-2020	
10.8+	Offer Letter between BioAtla, LLC and Scott Smith, dated August 2, 2018	S-1/A	333-250093	10.14	12-08-2020	
10.9+	Letter Agreement between BioAtla, LLC and Scott Smith, dated August 3, 2018	S-1/A	333-250093	10.15	12-08-2020	
10.10+	Severance Agreement between BioAtla, LLC and Scott Smith, dated August 20, 2018	S-1/A	333-250093	10.16	12-08-2020	
10.11+	Offer Letter between BioAtla, LLC and Richard Waldron, dated October 23, 2013	10-K	001-39787	10.19	02-28-2022	
10.12+	Severance Agreement between BioAtla, LLC and Richard Waldron, dated July 1, 2018	10-K	001-39787	10.20	02-28-2022	

Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Exhibit Filing Date	Filed/Furnished Herewith
10.13+	Offer Letter between BioAtla, LLC and Eric Sievers, dated June 17, 2019	10-K	001-39787	10.21	02-28-2022	
10.14+	Offer Letter between BioAtla, LLC and Christian Vasquez, dated October 22, 2015	10-K	001-39787	10.22	02-28-2022	
10.15+	Form of Indemnification Agreement between the Registrant and each of its executive officers or directors	S-1/A	333-250093	10.18	12-08-2020	
10.16	Lease Agreement with HCP Torreyana, LLC, dated June 2, 2017	S-1/A	333-250093	10.19	12-08-2020	
10.17	First Amendment to Lease with HCP Torreyana, dated January 16, 2019					X
10.18*	Master Clinical Trial Collaboration Agreement, dated January 5, 2022, by and between BioAtla, Inc. and Bristol-Myers Squibb Company	10-Q	001-39787	10.2	11-04-2022	
10.19*	First Amendment to Master Clinical Trial Agreement between BioAtla, Inc. and Bristol-Myers Squibb Company	10-K	001-39787	10.24	03-23-2023	
10.20*	China Clinical Trial Services Agreement, dated April 8, 2022, by and between BioAtla, Inc. and Himalaya Therapeutics Limited Company	10-Q	001-39787	10.1	08-09-2022	
10.21+	Amendment No. 2 to 2020 Equity Incentive Plan	10-K	001-39787	10.26	02-28-2022	
10.22+	Amendment No. 1 to Employee Stock Purchase Plan	10-K	001-39787	10.27	02-28-2022	
10.23*	Amendment No. 3 to Global Co-Development and Collaboration Agreement among BeiGene, Ltd., BeiGene Switzerland GmbH and BioAtla, Inc.	10-K	001-39787	10.28	02-28-2022	
10.24+	Form of Non-Employee Director Stock Option Agreement					X
10.25+	Form of Employee Stock Option Agreement					X
10.26+	Amended and Restated BioAtla Director Compensation Policy	10-K	001-39787	10.31	03-23-2023	
10.27+	BioAtla, Inc. Management Change of Control Severance Plan	8-K	001-39787	10.1	09-21-2022	
10.28	Open Market Sale Agreement[SM] dated as of January 6, 2023, between BioAtla, Inc. and Jefferies LLC	8-K	001-39787	1.1	01-06-2023	
23.1	Consent of Independent Registered Public Accounting Firm					X
24.1	Power of Attorney (included on signature page)					X
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1†	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.					X
97.1	Compensation Recovery Policy of BioAtla, Inc.					X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents					X
104	Cover Page Interactive Data File (formatted in iXBRL and contained in Exhibit 101)					X

† Furnished and not filed.
+ Indicates management contract or compensatory plan.
* Portions of this exhibit have been redacted in accordance with Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

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

BioAtla, Inc.

Date: March 26, 2024

By: /s/ Jay M. Short, Ph.D.
Jay M. Short, Ph.D.
Chief Executive Officer
(Principal Executive Officer and Authorized Signatory)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jay M. Short, Ph.D. and Richard A. Waldron as his or her true and lawful attorneys-in-fact, and each of them, with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with 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 requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, and either of them, or his or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Jay M. Short, Ph.D. Jay M. Short, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 26, 2024
/s/ Richard A. Waldron Richard A. Waldron	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 26, 2024
/s/ Scott Smith Scott Smith	Director	March 26, 2024
/s/ Lawrence Steinman, M.D. Lawrence Steinman, M.D.	Director	March 26, 2024
/s/ Mary Ann Gray, Ph.D. Mary Ann Gray, Ph.D.	Director	March 26, 2024
/s/ Susan Moran, M.D. Susan Moran, M.D.	Director	March 26, 2024
/s/ Sylvia McBrinn Sylvia McBrinn	Director	March 26, 2024
/s/ Edward Williams Edward Williams	Director	March 26, 2024

CORPORATE HEADQUARTERS

11085 Torreyana Road, San Diego, CA 92121
Telephone: (858) 558-0708
www.bioatla.com

BOARD OF DIRECTORS

Jay Short, Ph.D, Chairman, Chief Executive Officer & Cofounder of BioAtla, Inc.
Mary Ann Gray, Ph.D, President of Gray Strategic Advisors, LLC
Sylvia McBrinn, Strategic Advisor to PropelBio Partners
Susan Moran, M.D., M.S.C.E, Chief Medical Officer of RayzeBio, Inc.
Scott Smith, Chief Executive Officer of Viatris, Inc.
Lawrence Steinman, M.D., Professor of Neurology, Neurological Sciences and Pediatrics at Stanford University
Eddie Williams, Director of BioAtla, Inc.

EXECUTIVE OFFICERS

Jay Short, Ph.D, Chief Executive Officer & Cofounder
Richard Waldron, Chief Financial Officer
Eric Sievers, M.D., Chief Medical Officer
Chris Vasquez, Chief Accounting Officer, Controller and Secretary

INVESTOR RELATIONS

Richard Waldron, Chief Financial Officer
info@bioatla.com

LifeSci Advisors, LLC
bmackle@lifesciadvisors.com

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young, LLP, San Diego, California

STOCK LISTING & SYMBOL

Nasdaq Global Market Symbol: BCAB