Filed Pursuant to Rule 424(b)(3)
Registration No. 333-260440

PROSPECTUS SUPPLEMENT NO. 1
(to Prospectus dated November 3, 2021)

BioAtla, Inc.
Up to 2,678,600 Shares of Common Stock

This prospectus supplement supplements the prospectus dated November 3, 2021 (the "Prospectus"), which forms a part of our registration statement on Form S-1 (No. 333-260440). This prospectus supplement is being filed to update and supplement the information in the Prospectus with the information contained in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on February 28, 2022 (the "Annual Report"). Accordingly, we have attached the Annual Report to this prospectus supplement.

The Prospectus and this prospectus supplement relates to the offer and sale from time to time by the selling stockholders named in the Prospectus of up to 2,678,600 shares of common stock, par value $0.0001 per share ("Common Stock").
Our Common Stock is listed on the Nasdaq Global Market under the symbol "BCAB." On February 25, 2022, the closing price of our Common Stock was $6.64.

This prospectus supplement updates and supplements the information in the Prospectus and is not complete without, and may not be delivered or utilized except in combination with, the Prospectus, including any amendments or supplements thereto. This prospectus supplement should be read in conjunction with the Prospectus and if there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement.

See the section entitled "*Risk Factors*" beginning on page 6 of the Prospectus to read about factors you should consider before buying our securities.

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

The date of this prospectus supplement is February 28, 2022.

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, 2021

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

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, 2021, 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 $1.0 billion based on the closing sales price of $42.38 per share as reported on the Nasdaq Global Select Market.

As of February 25, 2022, the number of shares of the registrant's common stock outstanding was 35,829,127 and the number of shares of the registrant's Class B common stock outstanding was 1,492,059.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant's definitive proxy statement (the "Proxy Statement") relating to its 2022 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, 2021

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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 impact of the COVID-19 pandemic on our business, financial condition, results of operations, and prospects;
- 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; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

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, prior to the LLC conversion discussed below, to BioAtla, LLC and, after the conversion, 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.

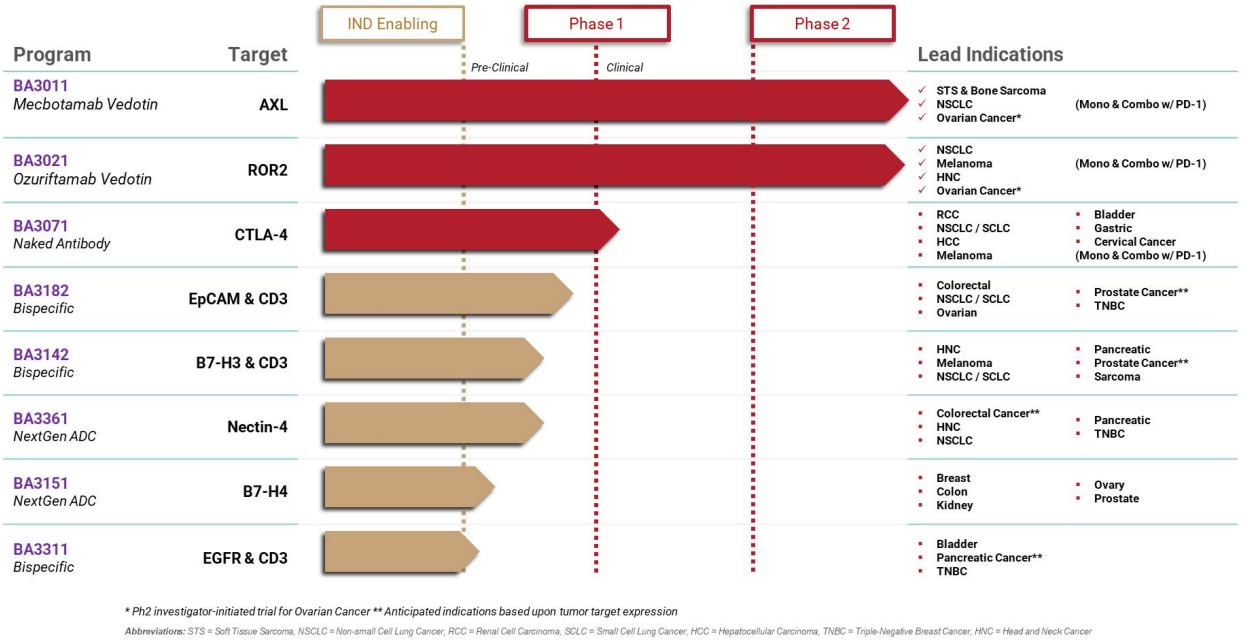
The broad applicability of our CAB technology allows us to develop a wide array of product candidate modalities, such as monoclonal antibodies, antibody-drug conjugates, or ADCs, T cell-engaging bispecific antibodies and chimeric antigen receptor T cells, or CAR-T cells. A key advantage of our application of the CAB technology to antibodies is that it allows us to selectively target antigens on tumor cells and minimizes or eliminates binding to these antigens on normal cells, which reduces the toxicity associated with traditional approaches. We have initiated potentially registration-enabling Phase 2 trials for our two latest stage CAB ADC product candidates targeting multiple cancer indications with mecbotamab vedotin (BA3011) targeting AXL in sarcoma and NSCLC and ozuriftamab vedotin (BA3021) targeting ROR2 in non-small cell lung cancer (NSCLC), melanoma, and head and neck cancer (SCCHN). The U.S. Food and Drug Administration, or the FDA, has reviewed the trial designs, but has not yet opined on whether the Phase 2 clinical trials will be sufficient to support regulatory approval. However, we intend to ask the FDA to consider this further at the upcoming interim data review point or points for these trials and indications. While we cannot assure you that the FDA will agree that the current clinical plan will be sufficient to support approval, the trial has been designed to allow us to adjust the clinical plan, if needed, after the interim read-out in order to better align with any potential FDA requirements. We are also supporting investigator-initiated trials for both mecbotamab vedotin and ozuriftamab vedotin in platinum-resistant ovarian cancer. We have observed encouraging initial clinical signs of response to treatment and a wide therapeutic window for a range of dosage and duration. Mecbotamab vedotin and ozuriftamab vedotin have the potential to address large unmet medical needs in indications that together account for more than 350,000 new cases of solid tumor cancers and 150,000 deaths per year in the United States alone. Additionally, we have initiated Phase 1 trials for multiple cancer indications in 2021 with dosing expect in the first half of 2022 for our CAB immuno-oncology antibody BA3071 targeting CTLA-4. BA3071 is designed to overcome the toxicity limitations of the currently approved anti-CTLA-4 antibodies and to improve patient outcomes. We also have several candidates in our IND-enabling preclinical pipeline that include CAB bispecific and ADC antibodies targeting unmet medical needs in multiple types of solid tumors.

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. While therapeutic antibodies have emerged as one of the most successful strategies for both solid and blood-based, or hematologic, malignancies, toxicity has narrowed the therapeutic window and ultimate potential of impacting disease, as many of the key targets on tumor cells are also prevalent on normal cells. The biology of tumor formation, or tumorigenesis, yields a unique microenvironment consisting of a complex mixture of tumor cells, stromal fibroblasts, endothelial cells and immune cells like microglia, macrophages and lymphocytes and the non-cellular components of extracellular matrix such as collagen, fibronectin, hyaluronan and laminin, among others. The process of tumor formation creates an altered, unique microenvironment in and around the tumor that is also physically and chemically distinct from healthy tissue, with regard to temperature, pressure, chemical composition and especially the acidity or pH. The tumorigenesis-driven shifts in microenvironment conditions further weaken the immune response and promote tumor growth. We have created and patented our CAB technology to enable the development of antibodies that are active in the tumor microenvironment, but inactive under normal physiological conditions, while ensuring target-specific binding on cancer cells. Our CAB technology aims to uniquely exploit the fundamental pH differences between the tumor and healthy tissue, increasing antibody binding selectivity and thereby potentially eliminating or greatly reducing healthy cell on-target, off-tumor toxicity. This enhanced selectivity 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.

Initially, we applied the reversible binding and precision capability of our CAB technology to develop next-generation ADC therapies. Traditional ADCs are a class of biologic drugs that are designed by attaching a toxic small molecule payload to an antibody, which then targets a specific antigen expressed on the target cell, but unfortunately, in most cases, this target is also present on normal tissue. Binding to the target on normal tissue leads to high on-target, off-tumor toxicity, which reduces the utility of traditional ADCs. Our CAB ADCs are designed to selectively bind to the antigens found in acidic pH conditions found in the tumor microenvironment, which has the potential to reduce off-tumor toxicity and related consequences. In addition, we developed CAB antibodies to immuno-oncology targets such as CTLA-4 for antitumor activity. We believe that our CAB technology can reduce the limitations resulting from systemic toxicities and expand the utility of this immuno-oncology therapy. We are also creating bispecific, T cell engaging, CAB antibodies that 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. This is a powerful approach to harness cytotoxic T cells to directly kill tumor cells with reduced toxicity.

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 product candidate, mecbotamab vedotin, or BA3011, is a CAB ADC that targets AXL, a protein kinase receptor that is highly 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. In preclinical studies, we have observed that BA3011 binds to AXL under conditions that reflect those in tumors. AXL has also 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 has been 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 have developed a biomarker assay that quantifies the AXL Tumor membrane Percent Score (0-100%), or TmPS. The TmPS measures the percentage of cancer cells within the tumor that expresses the AXL target expression generally on the tumor membrane which, consistent with industry standard, we use to identify those patients who we believe will be the most likely to respond to our product candidates. We believe that the larger percentage of cells expressing the target on the tumor membrane, the more likely it is that our product candidates may have the potential to provide clinical benefit.

We are developing mecbotamab vedotin as a potential therapeutic for multiple solid tumor types, including soft tissue and bone sarcoma, non-small cell lung cancer (NSCLC) and ovarian cancer, with other potential indications in the future. The Office of Orphan Drug Products (OODP) at the FDA granted Orphan Drug Designation to mecbotamab vedotin for the treatment of soft tissue sarcoma, and Phase 1 results in sarcoma patients were presented at the Connective Tissue Oncology Society (CTOS) 2021 Annual Meeting. Mecbotamab vedotin was generally well tolerated in this refractory sarcoma population. In the Phase 1 study, few patients discontinued due to an adverse event (two patients out of 26 or 7.7%) compared to discontinuation rates in most other clinical trials of ADCs. 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. Higher levels of AXL tumor membrane expression correlated with response to treatment. Of the seven sarcoma patients who had an AXL TmPS of greater than or equal to 70%, four of these obtained a confirmed partial response, including patients with leiomyosarcoma, undifferentiated pleomorphic sarcoma, and Ewing sarcoma. Prolonged response to therapy was observed in this ongoing study with the duration of response ranging from 33 to more than 60 weeks. Overall, we believe mecbotamab vedotin has the potential for a favorable benefit-risk profile, and importantly this is one of the few studies employing a putative biomarker which is not only highly expressed in sarcomas, but also may help select patients across multiple sarcoma subtypes who may benefit from therapy. In the ongoing potentially registration-enabling sarcoma Phase 2 study, patients are enrolled for therapy by prescreening for AXL expression. We are also conducting a Phase 2 study (BA3011-002) in AXL high NSCLC patients who have previously progressed on PD-1/L1, EGFR, or ALK inhibitor therapy. Planned interim analyses in the sarcoma and NSCLC trials are anticipated at the end of the first quarter and in the second quarter of 2022, respectively. In both Phase 2 indications, we are enrolling patients either as a monotherapy or in combination with a PD-1 inhibitor. In addition, a multi-center investigator-initiated Phase 2 clinical trial of mecbotamab vedotin in combination with a PD-1 inhibitor in patients with platinum-resistant ovarian cancer has begun enrollment and is expected to enroll approximately 20 patients.

Ozuriftabmab vedotin (BA3021): We are developing our second 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.

Employing a similar approach as with mecbotamab vedotin, we developed a TmPS quantitative assay based on ROR2 tumor membrane expression that we use to identify those patients who we believe will be the most likely to respond to our product candidates.

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 NSCLC, melanoma, and ovarian cancer. 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 high melanoma who have previously progressed on PD-1/L1 inhibitor and patients with ROR2 high NSCLC who have previously progressed on PD-1/L1, EGFR or ALK inhibitor therapy. A Phase 2 study in patients with ROR2 high SCCHN is anticipated to begin dosing patients in first half of 2022. In addition, a multi-center investigator-initiated Phase 2 clinical trial of ozuriftamab vedotin in combination with a PD-1 inhibitor in patients with platinum-resistant ovarian cancer has begun enrollment.

BA3071: Our third product candidate, BA3071, 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 currently is the only anti-CTLA-4 monoclonal antibody approved by the FDA. It is approved in combination with an anti-PD-1 antibody, nivolumab, for the treatment of multiple solid tumors, including melanoma, RCC, colorectal cancer and NSCLC. Patients treated with ipilimumab 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. The usage and dosage of ipilimumab is highly limited due to its safety profile, resulting in the average number of cycles on therapy not exceeding four cycles.

We are developing BA3071 as a potential therapeutic for multiple solid tumor indications, possibly including renal cell carcinoma, NSCLC, small cell lung cancer, hepatocellular carcinoma, melanoma, bladder cancer, gastric cancer and cervical cancer. We have initiated a Phase 1/2 dose-escalation trial of BA3071 as monotherapy and in combination with an anti-PD-1 antibody with expansion cohorts to be enrolled upon identification of the recommended dose.

Bispecific antibody programs: We have also 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 due to systemic immune activation.

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 EpCAM x CD3 bispecific. EpCAM, or epithelial cell adhesion molecule, 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 there was only one unconfirmed partial response observed among 65 patients at these low doses.

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. We are conducting IND-enabling studies for two CAB bispecific antibody product candidates, EpCAM/CD3 and B7-H3/CD3, and one next-generation CAB ADC, Nectin-4. We presently plan to file INDs in 2022 for EpCAM/CD3 and in 2023 for Nectin-4 and B7-H3/CD3. We also are evaluating additional candidates including EGFR/CD3 bispecific and B7-H4 as a next-generation CAB ADC candidate. Overall, we are advancing multiple pre-clinical assets and expect to file one IND in 2022, with the potential to submit up to three additional US INDs in 2023 for our CAB bispecific or ADC molecules.

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. Our CAB technology enables us to generate antibodies that bind to their targets under conditions found in the tumor, but not in healthy tissue. Therefore, we are able to generate antibodies to targets that to this point have been undruggable due to the lack of sufficient therapeutic window with existing antibody technologies. We are also able to use these antibodies to engage targets that exist not only in tumors, but in healthy tissue as well. This has the potential to reduce side effects and toxicity, one of the fundamental challenges of cancer therapies today, thereby expanding the realm of potential therapeutic antibodies. We believe that our proprietary 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 mecbotamab vedotin through regulatory approval and commercialization.** Clinical data from our Phase 1 trial with mecbotamab vedotin are supportive of its development in sarcomas, a set of cancers with a high unmet clinical need. We have initiated a potentially registration-enabling Phase 2 trial for mecbotamab vedotin in treatment refractory sarcoma patients (12 years of age or older), with an AXL TmPS of 50%, patients with an AXL TmPS equal or greater to 70% as the group for the primary analyses, and, if successful, we believe we can further advance mecbotamab vedotin through regulatory approval and commercialization. In addition, we have initiated a potentially registration-enabling Phase 2 trial in NSCLC using a primary AXL TmPS of 1%. We are using a quantitative biomarker assay/TmPS score to identify likely responders and to help enrich our clinical trial programs.
- **Advance ozuriftamab vedotin in PD-1/L1 refractory tumors through regulatory approval and commercialization.** We have observed antitumor activity in PD-1 refractory NSCLC and melanoma patients in our Phase 1 trial and have initiated a Phase 2 trial of ozuriftamab vedotin in each of these indications. We are using a quantitative biomarker assay/TmPS score to identify and stratify based the TmPS score the likely responders and to help enrich our clinical trial programs.

- **Advance BA3071 as a CAB- anti CTLA-4 immune checkpoint inhibitor to restrict T-cell activation to the tumor microenvironment.** The design of BA3071 is to provide the efficacy of ipilimumab, the only anti-CTLA-4 monoclonal antibody approved by the FDA, but with a significantly enhanced safety profile. 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.
- **Advance into clinical development multiple CAB bispecific and next generation CAB ADC candidates to further address areas of high unmet needs in treating solid tumors.** We believe that our next generation CAB-ADC platform further widens that therapeutic window by enhancing the linker-payload system. In addition, our first CAB EpCAM/CAB CD3 bispecific has recently demonstrated IND-enabling studies with a more than 80-fold improvement in the therapeutic window. Combining our CAB technology with our newly developed 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 December 31, 2021, we had a total of 584 patents and patent applications with 319 issued patents, 8 allowed applications and 257 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.
- **Selectively 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 over 30 targets for multiple diseases, most commonly cancer. Antibodies have become the new 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. For example, cetuximab targets an antigen that is highly expressed in colorectal cancer, but this antigen is also expressed in epidermal cells throughout the body. Consequently, treatment with cetuximab results in over 80% of patients developing skin toxicities that can severely impact patients' physical, psychological and social well-being and can lead to treatment discontinuation and dose reduction.

These examples, however, only represent antibodies where the therapeutic benefit clearly outweighs the consequences associated with the adverse events. There are many potential protein targets that do not offer such clear-cut therapeutic windows. 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.

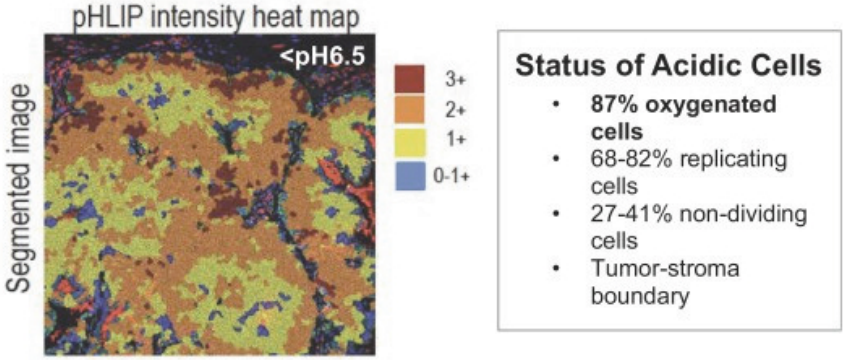
CAB leverages the low pH found in the tumor microenvironment

The tumor microenvironment has been widely implicated in tumorigenesis because it harbors tumor cells that interact with surrounding 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 environment 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. As shown in the figure described below, 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.

Shown below is a tumor “heat” map identifying the tumor cells that are surrounded by an acid microenvironment. Exploiting the established ability of pHLIP to label the membrane of cells exclusively under acidic conditions (≤ pH 6.5) *in vivo*, the cells within the acidic areas of the tumor *in vivo* can be identified at the histological level. Mice harboring human breast tumor xenografts were administered Cy7-labeled, or dyed, pHLIP peptide and the tumor tissues were later removed and processed for imaging. Shown on the left is a micrograph of the tumor with the cell-based segmentation data overlayed, including positional information relative to tumor edge. The degree of positivity generated in the above analysis was used to identify a 0-3+ positive cells. Note that the acidic areas extend beyond the traditional hypoxic core of the tumor into the aerobic and oxygenated cells at the invasive fronts at the tumor–stroma interface *in vivo*. Shown on the right is the breakdown of cancer cells types that are identified by pHLIP acidic cell staining *in vivo*. A majority of the cells identified are oxygenated and actively replicating tumor cells, and even the non-dividing cancers cells still maintain an acidic environment.

Tumor “Heat” Map



MIT Study: Rohani, et al (2019) Cancer Res 79:1952. (e.g. Breast Cancer Cells)

Tumors are highly acidic based on the uptake of pHLIP, a pH-sensitive probe. While the entire tumor is acidic, the lowest pH cells are observed in the replicating cells, which are glycolytic and often oxygenated, *i.e.*, the Warburg Effect.

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 was first described nearly a century ago and is the basis of modern tumor screening technologies. 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, even in the non-cancerous regions of tissues afflicted with cancer.

These pH differences provide a clear correlation between low pH and cancer, one that is borne out in the aforementioned experiments that measure the uptake by cells of the peptide pH tracer pHLIP. These cells are found to have high levels of lactate dehydrogenase, an enzyme that produces the sugar lactate, *i.e.*, lactic acid. Lactate production and secretion are well-known features of glycolysis. Similarly, there is a strong correlation between the uptake of pHLIP and the expression of markers of aggressive tumor growth such as Ki67.

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 may 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 initial product candidates, as well as in the conditions and levels of temperature, pressure and chemical composition in the tumor microenvironment.

Our CAB technology

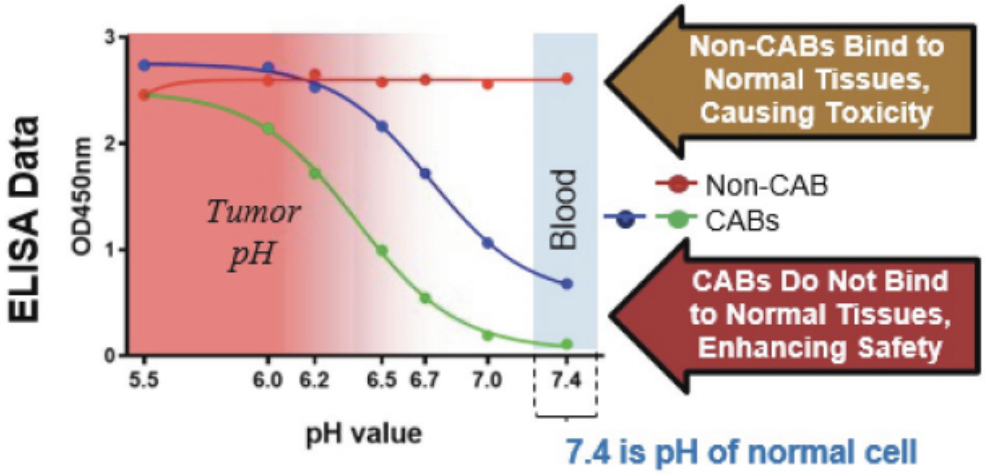
Our CABs are based on our patented protein discovery and engineering technology. We invented, developed and refined this technology, which we believe selectively activates the binding of proteins and antibodies to targeted cells in the tumor microenvironment based on differences in local conditions such as pH, temperature, pressure 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, pH7.4 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 physiological-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’s 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. As shown in the figure below, 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.

pH-dependent binding of CAB AXL antibodies vs. non-CAB AXL antibodies



CAB antibodies have pH-dependent binding. Traditional antibodies do not have pH-dependent binding in the pH range tested.

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, which may exhibit unacceptable toxicities such as cytokine release syndrome and neurological toxicity 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.

An important emerging class of antibodies is ADCs. An ADC is a modified antibody that generally has a chemotherapy agent attached to the antibody to enable more targeted chemotherapy treatment of a tumor.

Unfortunately, ADCs frequently bind to targets on normal cells and can lead to severe toxicities. In order to evaluate the CAB technology's ability to eliminate the on-target, off-tumor toxicities, we generated two ADCs during our preclinical testing: one using a CAB antibody to AXL and another using a traditional non-CAB AXL antibody. Within three days of dosing non-human primates with the traditional non-CAB ADC, the levels of alanine aminotransferase, or ALT, a sign of liver toxicity, increased sharply. Dosing with the CAB ADC resulted in minimal increase in ALT, supporting that on-target, off-tumor toxicity is reduced with the CAB ADC.

We also observed that the plasma concentration and half-life of the CAB ADC were higher than that of the traditional non-CAB ADC. We demonstrated a dose dependency of this observation, which indicates that the primary driver of this absence of TMDD effect with CAB ADC is due to the reduced binding of the CAB ADC to AXL outside of the tumor microenvironment.

Our CAB technology was studied in robust Phase 1 clinical trials for our two leading clinical programs, which have shown the following:

- Objective antitumor responses: We observed multiple confirmed partial clinical responses (at least 30% reduction in tumor size for at least two consecutive time points) in our Phase 1 data for both mecbotamab vedotin and ozuriftamab vedotin, including in one patient tumor volume shrinkage of more than 90% and another with a complete response (CR), and several patients who remain without tumor progression for more than one year.
- Antitumor activity correlates with a proprietary biomarker: The presence of the relevant target on a high percentage of tumor cells appeared to correlate with increased antitumor activity.
- Safety and tolerability: Mecbotamab vedotin and ozuriftamab vedotin were generally well-tolerated at the recommended Phase 2 dose range, which is positively differentiated from both preclinical and cross-trial trial results for a similar non-CAB ADC. Side- effects have been generally manageable with our CAB ADC product candidates, with some patients able to receive more than a year of treatment.

Through the use of our proprietary technology, we have developed CAB antibodies, 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 tumors 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.

Clinical trials

Mecbotamab Vedotin (BA3011)

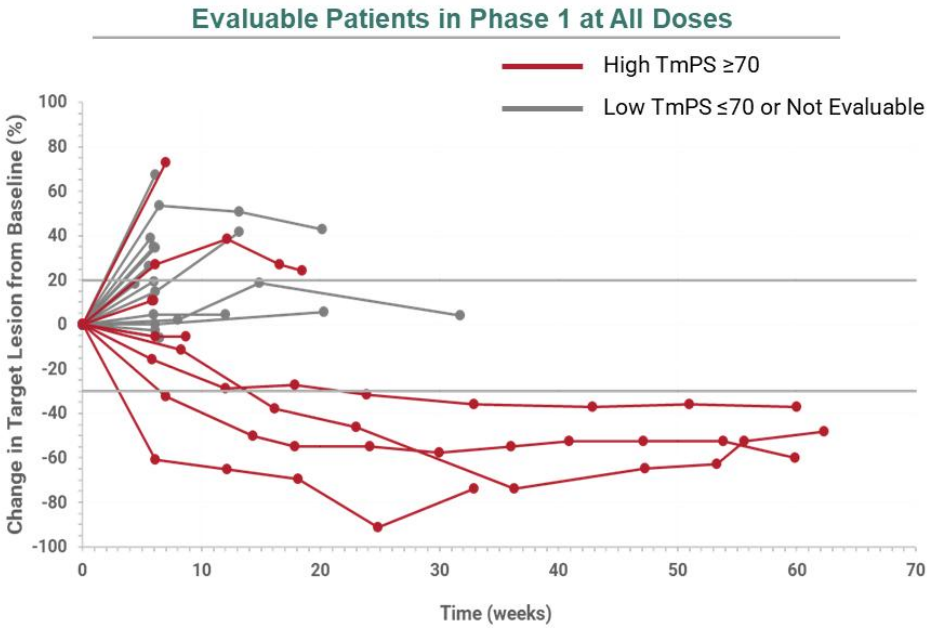
Phase 1 clinical trial

We have completed a Phase 1 trial of mecbotamab vedotin in patients with advanced solid tumors, including sarcoma, pancreatic cancer and NSCLC who were refractory or resistant to standard therapies. In the Phase 1 trial, a total of 60 patients, including 26 patients with sarcoma, 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 Phase 1 sarcoma patients on average had received four or more prior lines of therapy. The solid tumor types enrolled in this study were: soft tissue sarcoma (22 subjects), pancreatic (12 subjects), NSCLC (4 subjects), colorectal (4 subjects), melanoma (3 subjects), bladder (2 subjects), endometrial (2 subjects), Ewing sarcoma (2 subjects), non-TNBC, osteosarcoma, chondrosarcoma, myoepithelial carcinoma, adenoid cystic carcinoma, small cell lung, renal cell carcinoma and mesothelioma of the pleura (1 subject each).

The main goals of this trial were to evaluate the safety, tolerability, antitumor activity, pharmacokinetics and immunogenicity of BA3011 in solid tumor patients. Based upon the overall safety and response rates, the recommended Phase 2 dose was determined to be 1.8 mg/kg delivered every two weeks (Q2W).

Antitumor activity

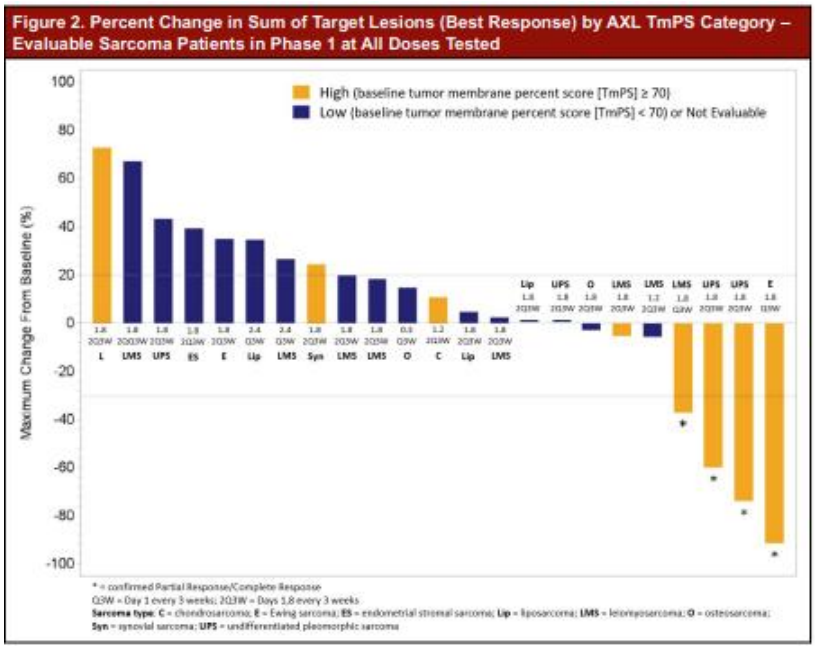
We evaluated overall response (OR), one of our secondary endpoints, and observed five confirmed partial responses (a reduction of at least 30% in the size of the tumor), four in patients with sarcomas and one with NSCLC. These responses have been shown to be durable (8-15 months in sarcoma patients; duration of response, or DoR, is one of our secondary endpoints). Further, additional patients have experienced prolonged progression-free intervals, a period of time where the existing tumor did not measurably increase in size by more than 20% and no new tumors were known to develop. The toxicities observed were consistent with those described with MMAE-based ADCs and were well-tolerated at the exposure subsequently employed for Phase 2. Importantly we have not observed adverse events that appeared 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.



Antitumor response over time by AXL expression for evaluable sarcoma patients enrolled in Phase 1 trial at all BA3011 doses tested

We developed and validated, as required by CLIA (the Clinical Laboratory Improvement Amendments, or CLIA, which establishes federal quality standards for laboratory testing), an AXL immunohistochemical assay to quantify the level of target expression on the tumor membrane and cytoplasm. An independent board-certified pathologist scored all samples according to this TmPS scoring scheme determined by us during the clinical validation phase, as well as during the Phase 1 trial.

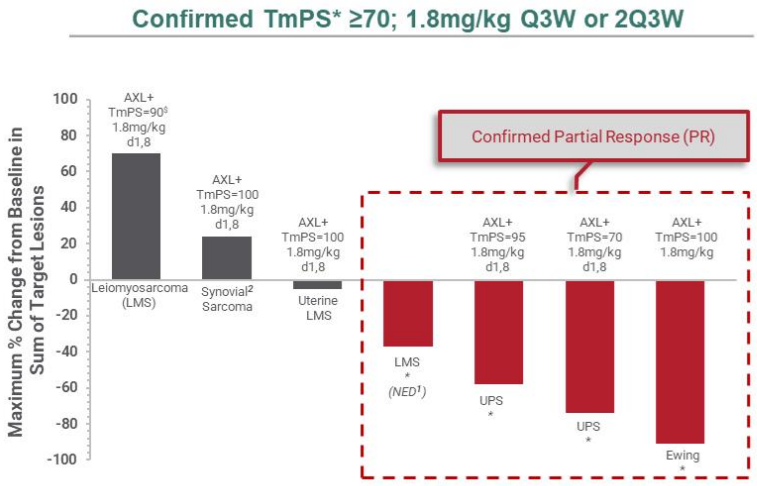
We observed that approximately 57% of sarcoma patients screened for enrollment had an AXL TmPS of 70% or above. In addition, we identified a correlation between the expression of AXL on the membrane of tumor cells and the observed antitumor clinical response as shown in the figure below. Four of seven sarcoma patients with a confirmed AXL TmPS of 70% or above who were dosed with 1.8 mg/kg of BA3011 Q3W or 2Q3W achieved a confirmed partial response.



Change in sum of target lesions (best response) by AXL TmPS category for Phase 1 evaluable patients at all BA3011 doses tested

Focusing on the subset of sarcoma patients who were dosed with 1.8 mg/kg Q3W or 2Q3W of BA3011 with TmPS of 70%, we observed a correlation of the AXL TmPS and antitumor response. As shown below, five out of six patients with multiple subtypes of sarcoma experienced reductions in tumor volume and four of these five patients achieved confirmed partial responses (observed response for at least two consecutive time points). We are confirming this observed correlation and the TmPS cut-off of 70% or more in our ongoing Phase 2 studies.

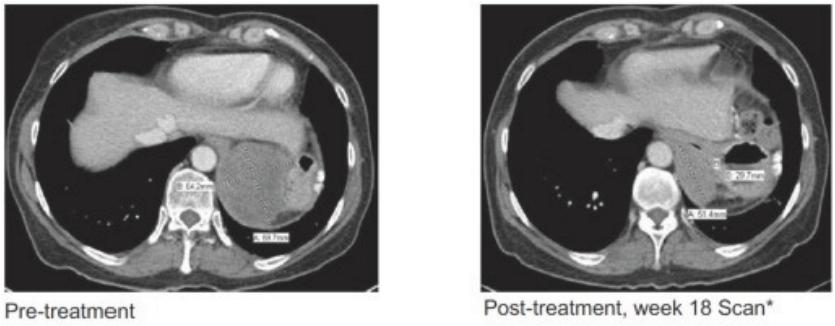
Best response for sarcoma patients with confirmed TmPS of 70% or above administered 1.8mg/kg Q3W or 2Q3W



Notes:
All patients: Multiple cycles of antineoplastic agents received prior to starting treatment with BA3011
*AXL Tumor membrane Percent Score or TmPS = % Score ≥1+; §Tissue biopsy from resection, over 1 year old prior to trial entry
1 NED = No evidence of disease; 2 Synovial sarcoma patient delayed treatment due to unrelated SAE led to progression

One patient with leiomyosarcoma who had experienced failure of multiple prior treatments had a 37% reduction in tumor volume while receiving 1.8 mg/kg Q3W BA3011, as shown in the figure below. After over a year of treatment with BA3011, the residual tumor mass was reduced to a sufficient degree, enabling a successful surgical resection.

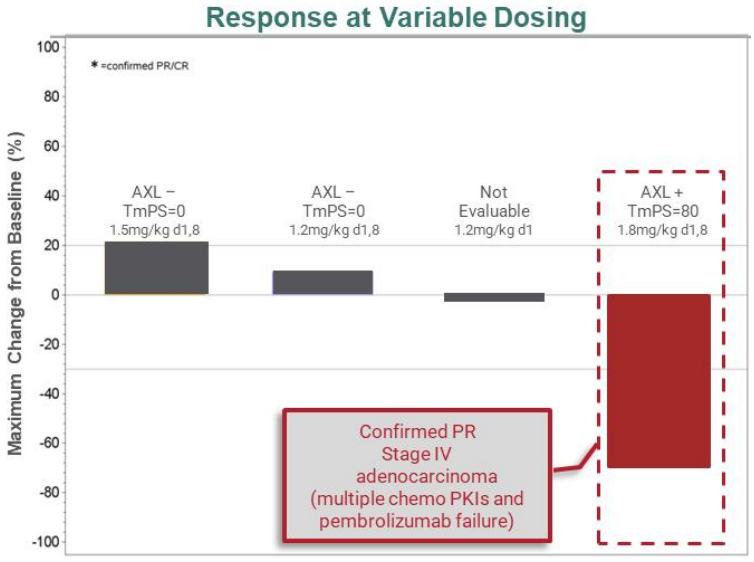
CT scan of leiomyosarcoma patient after BA3011 treatment



CT scan of a 70 mm leiomyosarcoma tumor which decreased in size with BA3011 treatment (confirmed PR) and after a year of therapy was removed by surgical resection.

Of the four patients with NSCLC enrolled in our Phase 1 clinical trial, two were AXL negative with a TmPS of 0%, one was not evaluable, and one was AXL positive with a TmPS of 80%. Prior to BA3011 treatment, the AXL positive patient with stage IV adenocarcinoma experienced failure from prior treatments, including treatment with a PD-1 inhibitor (pembrolizumab). As shown below, this patient experienced a partial response characterized by approximately 70% tumor shrinkage with BA3011 delivered at 1.8 mg/kg on days 1 and 8, every three weeks (2Q3W).

One of four NSCLC patients enrolled in Phase 1 BA3011 trial was the only patient with an AXL TmPS >=70%.and had a partial response.



Safety

Mecbotamab vedotin was generally well-tolerated. We have not observed adverse events that appear to be related to on-target injury of normal, AXL-expressing tissues. We believe that toxicities observed at the maximally tolerated dose and lower were manageable and off-target effects of free MMAE were consistent with those described with other marketed MMAE-based ADCs. The estimated half-life of mecbotamab vedotin was approximately four days, which is twice the 1.9-day half-life reported for enapotamab vedotin, a non-CAB ADC targeting AXL. We believe this difference may be due to the decreased TMDD resulting from the lack of binding of mecbotamab vedotin to AXL outside of tumors.

In the Phase 1 trial, the 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: AST/ALT increased) or metabolic disturbances (AEs: hyponatremia, hypokalemia). There were 24 (37.5%) subjects who reported a serious TEAE (SAE), and in 7 (10.9%) of those subjects that serious TEAE was considered related to treatment.. At the anticipated Phase 2 exposure level (1.8mg/kg Q2W), BA3011 was generally well-tolerated. For 1.8 mg 1Q3W there were 2 subjects (22% ; 2/9) who experienced treatment related Grade 3-4 AEs (, vomiting and neutrophil count decrease);for 1.8 mg 2Q3W there were 13 subjects (52%;13/25) who experienced treatment related Grade 3-4 AEs (neutropenia (x3), hypokalemia (x3), , anemia, nausea, febrile neutropenia, fatigue, lymphocyte count decrease, blood bilirubin increase and lipase increase)For 1.8mg/kg Q3W, there were 4 subjects who experienced an SAE (44%; neutrophil count decrease, intestinal obstruction, lower limb fracture, and sepsis caused by E. coli); for 1.8mg/kg 2Q3W there were11 subjects who experienced an SAE (44%; nausea, pyrexia, lipase increased, hyponatremia, syncope, corneal perforation, hypercalcaemia, gastritis, pneumonia, hepatic encephalopathy, and edema of lower extremities) and of these SAEs, fewer were deemed related to treatment by the investigator (for 1.8mg/kg Q3W: 1 SAE (11.1%; neutrophil count decrease); 1.8mg/kg 2Q3W: 3 SAEs (12%; hepatic encephalopathy, lipase increased and gastritis). For 1.8mg/kg 2Q3W, 2 related AEs led to treatment discontinuation (Grade 2 peripheral neuropathy and Grade 2 fatigue). No AEs led to treatment discontinuation for 1.8mg/kg Q3W.

Overview of adverse events in mecbotamab vedotin (BA3011) Phase 1 trial for patients administered 1.8mg/kg Q3W (d1) or 2Q3W (d1,8) (safety population)

Characteristic	BA3011 1.8 mg/kg Q3W (N=9)	BA3011 1.8 mg/kg 2Q3W (N=25)
Any AEs	9 (100%)	25 (100%)
Related AEs with CTCAE1 Grade 3 or 4[2]	2 (22%)	13 (52%)
Any related serious AEs[2]	1 (11%)	3 (12%)
AEs leading to death	1 (11%)	0
Related AEs leading to death[2]	0	0
Related AEs leading to treatment discontinuation[2]	0	2 (8%)

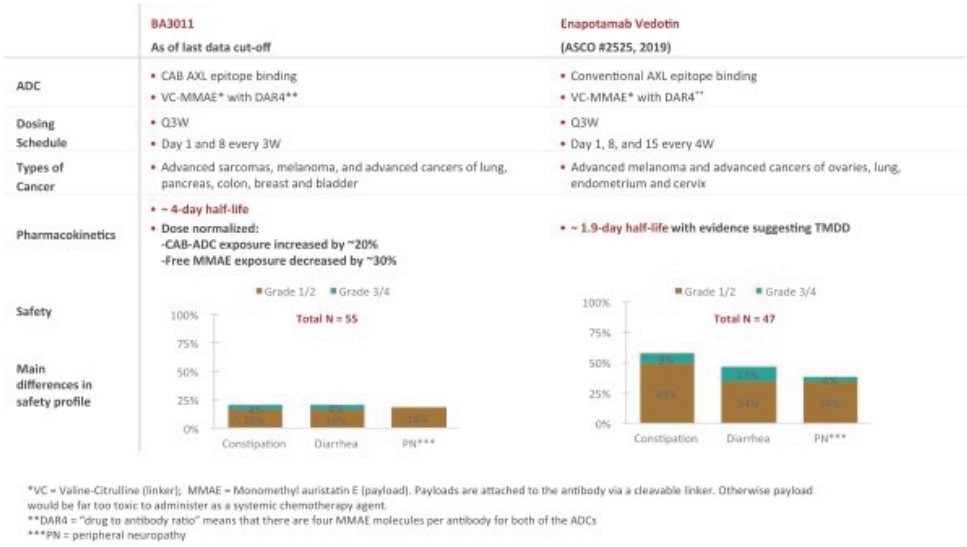
1. CTCAE: Common Terminology Criteria for Adverse Events. The NCI Common Terminology Criteria for Adverse Events is a descriptive terminology which is utilized for AE reporting. A grading (severity) scale is provided for each AE term.
2. As assessed by the investigator. Missing responses are counted as related.

We believe that our CAB AXL ADC, mecbotamab vedotin, compares favorably to enapotamab vedotin, a non-CAB AXL ADC with regard to safety and key pharmacokinetic properties. Comparing across the two Phase 1 trials, both ADCs: (i) were designed to deliver 4 MMAE molecules per antibody (DAR4 loading), (ii) employed similar ADC doses and (iii) enrolled comparable patients with advanced cancer who had experienced treatment failure of prior regimens (see figure below). As a key difference, mecbotamab vedotin was designed to only bind to the AXL target expressed by tumor while enapotamab vedotin would be anticipated to bind to the AXL target throughout the body.

Notably, the estimated half-life of mecbotamab vedotin was approximately four days, which is twice the 1.9-day half-life reported for enapotamab vedotin. We believe this difference may be due to the decreased TMDD resulting from the lack of binding of mecbotamab vedotin to AXL outside of tumors. With respect to reported toxicity comparisons, constipation is believed to be an on-target delivery of MMAE to normal gut tissues that express the AXL target. Despite including a risk mitigation plan in enapotamab vedotin's trial protocol (a prophylactic stool-softener medication in all patients), the clinical data presented at ASCO 2019 showed that AEs of constipation Grade 1-2 were reported in 49% of the patients and Grade 3-4 in 9% of patients. The rate of constipation reported with mecbotamab vedotin (26% Grade 1-2 and 43% Grade 3-4) was approximately 2 or 3-fold lower for Grade 1-2 and Grade 3-4 TAEs, respectively. We believe the lower observed rates of constipation observed among the mecbotamab vedotin treated patients were typical for an advanced cancer population who commonly receive pain medications that can also cause constipation. While supportive of a reduced toxicity benefit from CAB technology, these comparisons are derived from cross-trial analyses, and would not be included as part of our labeling.

Adverse events, such as peripheral neuropathy, are commonly seen with other ADCs and may be due to free circulating MMAE. Clinical data presented at ASCO 2019 for enapotamab vedotin showed that 38% of the patients had peripheral neuropathy (all Grades) with 2 patients reporting Grade 3-4 AEs. The rate of peripheral neuropathy (all Grade; no Grade 3-4) reported for mecbotamab vedotin (28%) was meaningfully lower than the rate reported with enapotamab vedotin and is believed to be due to the advantageous pharmacokinetic characteristics of a CAB ADC vs. a non-CAB ADC.

At a dose of 2.4 mg/kg Q3W mecbotamab vedotin, two patients experienced dose-limiting toxicities: one with Grade 3 febrile neutropenia and the other with Grade 4 hyperglycemia. Dosing continued at the 2.4 mg/kg with prophylactic administration of pegfilgrastim without any additional dose limiting toxicities. Dosing above 2.4 mg/kg was terminated due to one patient who experienced Grade 4 febrile neutropenia and cardio-respiratory arrest at 3 mg/kg likely related to delayed hepatic and renal excretion of MMAE.



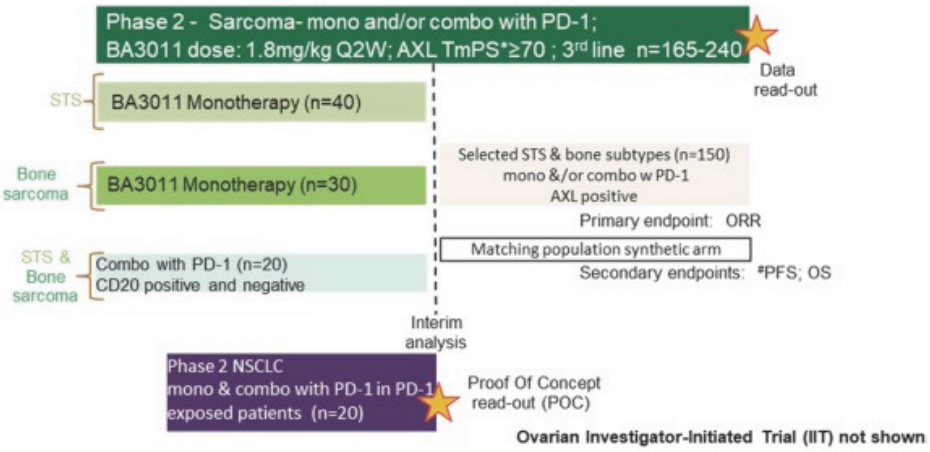
*VC = Valine-Citrulline (linker); MMAE = Monomethyl auristatin E (payload). Payloads are attached to the antibody via a cleavable linker. Otherwise payload would be far too toxic to administer as a systemic chemotherapy agent.
**DAR4 = "drug to antibody ratio" means that there are four MMAE molecules per antibody for both of the ADCs
***PN = peripheral neuropathy

Phase 2 clinical trial

We are conducting a Phase 2, potentially registration-enabling trial with mecbotamab vedotin, enrolling 90 soft-tissue and bone sarcoma patients, with interim analysis anticipated in early 2022 and the complete data set expected in 2023. In addition, we have initiated a Phase 2 trial in NSCLC with mecbotamab vedotin as monotherapy and in combination with an anti-PD-1 agent in patients who have experienced prior disease progression on a PD-1/L1 inhibitor and have a TmPS of 1% or greater. The FDA has reviewed the trial designs, but has not opined on whether Phase 2 clinical trials will be sufficient to support regulatory approval. However, we intend to ask the FDA to consider this further at the planned interim data review point or points for each clinical trial. We cannot assure you that the FDA will agree that such data will be sufficient to support approval. A summary of our clinical development plan for mecbotamab vedotin is below.

Additionally, a multi-center investigator-initiated trial of mecbotamab vedotin led by the Canadian Cancer Trials Group, or CCTG, in platinum-resistant ovarian cancer patients has begun enrollment.

Clinical development plan for mecbotamab vedotin (BA3011), which includes multiple Phase 2 trials



*TmPS= Tumor membrane Percent Score- Scores range from 0 to 100.
#PFS = progression-free survival, OS = overall survival

Sarcoma Phase 2 trial:

This Phase 2 trial is an open-label trial to evaluate the efficacy and safety of mecbotamab vedotin alone and in combination with an anti-PD-1 agent in adult and adolescent patients with AXL-expressing TmPS >= 70%, and advanced, refractory sarcoma who have measurable disease by RECIST Version 1.1 criteria and have documented progression according to RECIST Version 1.1 criteria within the six months prior to enrollment. In addition, there is an exploratory cohort of patients with AXL-expressing TmPS of 50-69%. To enroll, patients either had to be ineligible for chemotherapy or had received at least one regimen containing anthracycline and a maximum of three previous lines of systemic therapy for metastatic disease (no more than two lines of combination regimens), including pazopanib, trabectedin, eribulin mesylate or tazemetostat, if applicable, per regional prescribing information. Patients who met the enrollment criteria were assigned to receive either mecbotamab vedotin alone or in combination with an anti-PD-1 agent (for patients 18 years old and above: 240 mg every two weeks (Q2W); for patients 12-17 years old: 3 mg/kg Q2W IV infusion). Patients with tumors showing B-cell infiltration (per immunohistochemistry, or IHC, assay) are preferentially assigned to receive mecbotamab vedotin in combination with an anti-PD-1 agent. Based on data from the Phase 1 part of the trial, the dose of mecbotamab vedotin for Phase 2 is 1.8 mg/kg Q2W.

In Part 1 of this Phase 2 trial, seven cohorts of approximately 10 patients per sarcoma subtype in the monotherapy arm are enrolled:

Soft tissue sarcoma:

- Leiomyosarcoma
- Synovial sarcoma
- Liposarcoma
- All other soft tissue sarcomas, except gastro intestinal stromal tumors, dermatofibrosarcoma protuberans, inflammatory myofibroblastic tumor and malignant mesothelioma

Bone sarcoma:

- Osteosarcoma
- Ewing sarcoma
- Other bone sarcomas, including undifferentiated pleomorphic sarcoma, malignant fibrous histiocytoma, and chondrosarcoma

In addition, two combination cohorts (mecbotamab vedotin with an anti-PD-1 agent) are enrolling up to approximately 10 patients each, of any sarcoma subtype. Patients in one arm will have a tumor showing B-cell infiltration and patients in the other arm will not.

Tumor assessment occurs approximately every 6 weeks from cycle 1 day 1 of treatment, or C1D1, until 12 weeks, and every 8 weeks thereafter. Pharmacokinetic, pharmacodynamic, immunogenicity and biomarker assessments will also be performed at various time points.

An interim analysis is conducted for each subtype or treatment after approximately 10 patients in the subtype or treatment have been followed for at least 12 weeks after the initiation of treatment. Following interim analysis, accrual to the subtype or to a treatment (i.e., mecbotamab vedotin alone or in combination with an anti-PD-1 agent) may proceed to Part 2 of the trial if one or more patients with a response (i.e., confirmed or unconfirmed complete response or partial response) or progression-free rate at 12 weeks is >= 40%. Several cohorts already have qualified to proceed to this Part 2 of the trial. Approximately 150 additional patients may be enrolled for sarcoma subtypes that meet the threshold. The accrual of patients to a specific subtype or to one or both treatment regimen(s) (i.e., mecbotamab vedotin alone and/or mecbotamab vedotin in combination with an anti-PD-1 agent) can be put on hold at any time based on evaluation of available data or by the Independent Data Monitoring Committee, or IDMC, at any time upon review of safety data. Treatment for all enrolled patients will continue until disease progression, unacceptable toxicity, or other reason for treatment discontinuation.

NSCLC Phase 2 trial:

This is a multi-center, open-label, Phase 2 study designed to evaluate the efficacy and safety of mecbotamab vedotin alone and in combination with an anti-PD-1 agent in patients with AXL-expressing TmPS >=1%, metastatic NSCLC who have measurable disease by RECIST v1.1 criteria and have documented progression according to RECIST v1.1 criteria within the 6 months prior to enrollment. To enroll, patients must have prior disease progression on a PD-1/L-1 inhibitor (either monotherapy or in combination with another therapy such as ipilimumab). Patients with EGFR or anaplastic lymphoma kinase (ALK) genomic tumor aberrations should have had disease progression on FDA-approved therapy for these aberrations.

Patients who meet enrollment criteria will be assigned to receive either mecbotamab vedotin alone or in combination with an anti-PD-1 agent (240 mg every 2 weeks (Q2W)). For the first 20 patients (Part 1), treatment assignment will be determined by the sponsor and the medical monitor based on the patient's prior experience with PD-1/L1 treatment. To be eligible for the PD-1 combination arm, patients must have acceptably tolerated prior PD-1/L1 treatment. In Part 2, up to approximately 200 additional patients may be enrolled depending on observed efficacy at interim analysis. If both monotherapy and combination therapy are further pursued post interim analysis, patients that have acceptably tolerated prior PD-1/L1 treatment will be randomized 1:1 to receive either mecbotamab vedotin alone or mecbotamab vedotin in combination with an anti-PD-1 agent. Randomization will be stratified according to histology (squamous vs. non-squamous) and the number of prior systemic regimens (< 2 vs. < 3). Patients that have not acceptably tolerated prior PD-1/L1 treatment will be assigned to the mecbotamab vedotin monotherapy arm of the study. Based on data from the Phase 1 study, the dose of mecbotamab vedotin for Phase 2 is 1.8 mg/kg Q2W. A dose reduction to 1.5 mg/kg Q2W may be implemented if deemed warranted by the IDMC.

Tumor assessment will occur approximately every 6 weeks from C1D1 until 12 weeks, and every 8 weeks thereafter. Pharmacokinetic, pharmacodynamic, immunogenicity and biomarker assessments will be performed at various time points.

An interim analysis will be conducted after approximately 20 patients (e.g. 10 patients on mecbotamab vedotin monotherapy arm and 10 patients in the mecbotamab vedotin and anti-PD-1 agent combination arm) have the potential to be followed for at least 12 weeks after the initiation of investigational product. Following interim analysis, accrual to a treatment (i.e., mecbotamab vedotin alone or in combination with an anti-PD-1 agent) may be put on hold if the number of patients with a response (i.e., confirmed or unconfirmed complete response, partial response or stable disease) are below a pre-defined threshold. Depending on observed efficacy at the interim analysis, additional NSCLC patients may be enrolled for a total of up to approximately 200 patients (100 patients in each of the 2 treatment groups) with AXL-expressing, metastatic NSCLC. The accrual of patients to one or both treatment regimen(s) (i.e., mecbotamab vedotin alone and/or mecbotamab vedotin in combination with an anti-PD-1 agent) can be put on hold at any time based on evaluation of available data. Treatment for all enrolled patients will continue until disease progression, unacceptable toxicity, or other reason for treatment discontinuation.

Ozuriftamab Vedotin (BA3021)

Phase 1 clinical trial

We have completed the dose escalation part of a Phase 1 clinical trial of ozuriftamab vedotin in patients with locally advanced unresectable or metastatic solid tumors including NSCLC and melanoma, who were refractory or resistant to standard therapies. As shown below, cohorts 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). In Phase 1, 60 subjects were enrolled into 9 dose cohorts: 0.3 mg/kg Q3W (1 subject), 0.6 mg/kg Q3W (1 subject), 1.2 mg/kg Q3W (1 subject), 1.8 mg/kg Q3W (3 subjects), 2.4 mg/kg Q3W (16 subjects), 3.0 mg/kg Q3W (19 subject), 3.3 mg/kg Q3W (5 subjects), 1.2 mg/kg 2Q3W (3 subjects), 1.5 mg/kg 2Q3W (3 subjects), and 1.8 mg/kg 2Q3W (8 subjects). The solid tumor types enrolled in this study were: soft tissue sarcoma (40 subjects), NSCLC (6 subjects), melanoma (2 subjects), pancreatic (2 subjects), non-TNBC (2 subjects), TNBC (2 subjects), colorectal, GIST, urachus, ampulla of vatter, rectal carcinoid and head and neck (1 subject each).

The main goal of this trial was to evaluate the safety, tolerability, antitumor activity, pharmacokinetic and immunogenicity of ozuriftamab vedotin in solid tumor patients. Based upon the overall safety and response rates, the recommended Phase 2 dose is 1.8 mg/kg delivered every two weeks (Q2W). The trial's objectives were the following:

Primary

- To define the safety profile, including DLT, and determine the MTD and/or RP2D and other safety parameters for ozuriftamab vedotin in patients with advanced solid tumors.

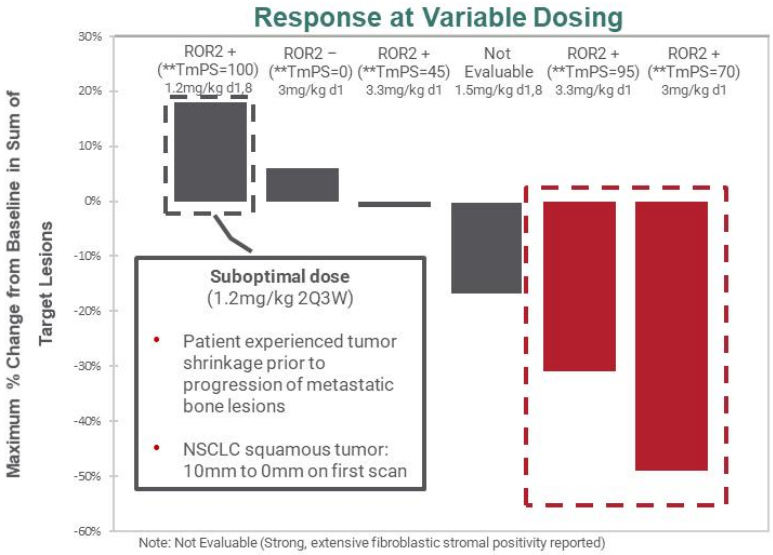
Secondary

- To assess antitumor activity of ozuriftamab vedotin including endpoints such as OR, DoR, disease control, time-to-response, and ORR, according to RECIST Version 1.1.
- To assess the pharmacokinetics of ozuriftamab vedotin.
- To evaluate the immunogenicity of ozuriftamab vedotin.

Antitumor activity

We evaluated OR, one of our secondary endpoints, as shown in the figure below. At various dose levels, treatment with ozuriftamab vedotin has resulted in a complete response in one patient with metastatic melanoma. This patient remains progression free more than two years after initiating therapy. In addition, two patients with NSCLC (~31% and ~49% tumor reduction) and one patient with advanced head and neck cancer (~54% tumor reduction) were partial responses.

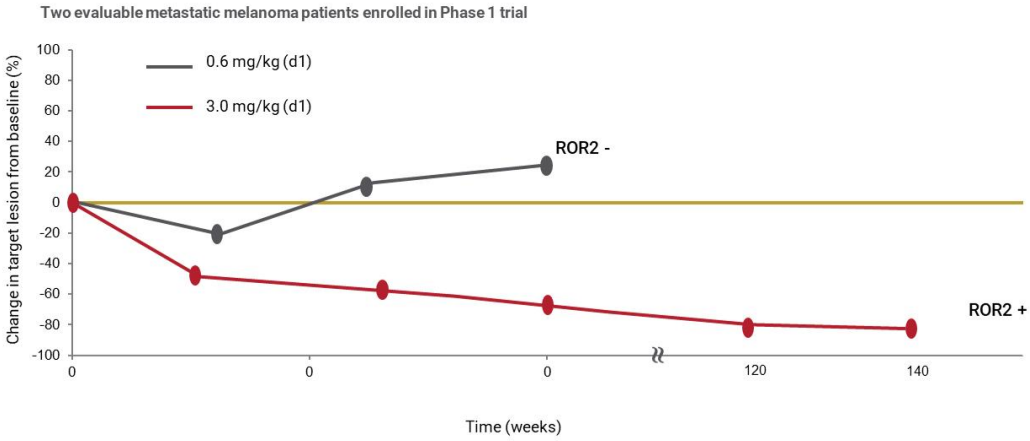
Of the six NSCLC patients enrolled in the dose escalation phase, two patients achieved a durable partial response (duration of response is one of our secondary endpoints) and a third experienced tumor reduction to a lesser degree (change from baseline in tumor size is one of our secondary endpoints, as shown below). Similar to the observed correlation of antitumor activity with higher levels of tumoral membrane AXL expression, as shown below, the two NSCLC patients with partial responses to ozuriftamab vedotin had ROR2 TmPS of at least 70%. We were not able to characterize ROR2 TmPS for the third patient who also experienced tumor shrinkage. Another patient with late stage NSCLC and bone metastases and a ROR2 TmPS of 100%, treated with a suboptimal dose of ozuriftamab vedotin (1.2mg/kg 2Q3W), experienced tumor shrinkage prior to progression of their metastatic bone lesions. All NSCLC patients who enrolled in this trial had previously been treated with PD-1 therapy.



NSCLC patients enrolled in ozuriftamab vedotin (BA3021) Phase 1 trial by ROR2 TmPS. Tumor membrane ROR2 expression was associated with antitumor response in two of the five NSCLC patients with evaluable ROR2 TmPS

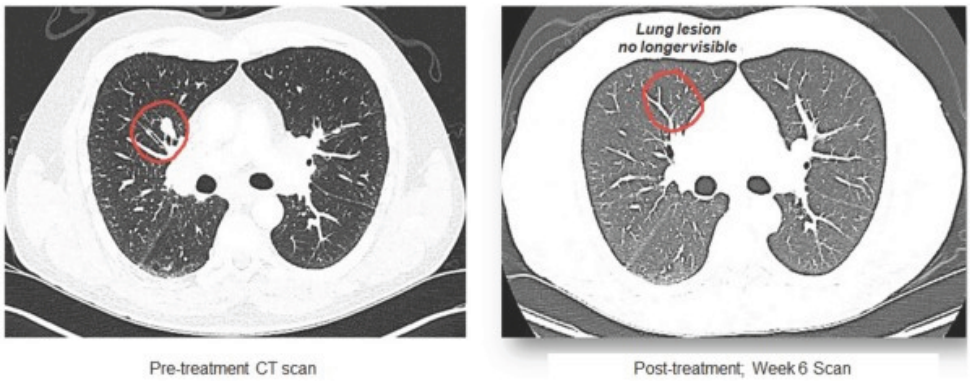
Two metastatic melanoma patients were enrolled in the initial part of the trial, as shown below. The ROR2 positive patient achieved a significant durable partial response (duration of response is one of our secondary endpoints). Furthermore, this patient, who had previously experienced failure of both nivolumab and nivolumab plus ipilimumab, achieved complete response and remains without disease progression more than two years after initiating ozuriftamab vedotin.

All evaluable metastatic melanoma patients enrolled in ozuriftamab vedotin (BA3021) Phase 1 trial by ROR2 TmPS



The metastatic melanoma patient who achieved a complete response experienced clearance of metastatic lung lesions. Illustrated below is one of the two lung lesions that cleared. Moreover, a pretreatment biopsy of an involved, abnormally enlarged cervical lymph node showed active melanoma. Subsequently, an on-treatment biopsy of the same node demonstrated no evidence of melanoma.

Clearance of lung lesions in metastatic melanoma patient who received ozuriftamab vedotin (BA3021)



Pre-treatment and post-treatment CT scans of one of two lung lesions that were both cleared in a metastatic melanoma patient who received ozuriftamab vedotin (BA3021)

In addition, one head and neck cancer patient achieved a partial response with a 54% reduction in tumor size.

Safety

Similar to mecbotamab vedotin, ozuriftamab vedotin was 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: hyponatremia, hypokalemia). There were a total of 24 (40%) patients who experienced an SAE, 12 (20%) of which were serious TEAEs that were considered related to treatment. At the Phase 2 exposure levels (1.8mg/kg Q2W), ozuriftamab vedotin was generally well tolerated. For 1.8 mg 1Q3W33.3% (1/3) of subjects experienced treatment-related Grade 3-4 AEs (anemia) and 0% had an SAEs (0); for 1.8 mg 2Q3W:62% (5/8) of subjects experienced treatment-related Grade 3-4 AEs (fatigue, hyponatremia, multiorgan failure, peripheral neuropathy and hyperglycemia) and 50% experienced an SAEs (4/8%; infected biloma, pyrexia, multiorgan failure and hyperglycemia). Three of these SAEs, were deemed related to treatment by the investigator (37.5%; pyrexia, multiorgan failure and hyperglycemia). For 1.8mg/kg 2Q3W, one subject (12.5%) experienced a TEAE that led to death and was considered potentially related to study treatment.

The subject was a 47-year-old female with a history of metastatic TNBC previously treated with bilateral mastectomy, radiotherapy, doxorubicin + cyclophosphamide + paclitaxel, capecitabine, nab-paclitaxel, atezolizumab, and sacituzumab govitecan. According to the investigator, no clear etiology of the subject's signs and symptoms was identified. The investigator was unable to identify another clear-cut cause of the subject's medical deterioration; however, as these events were temporally following her infusion of study drug, the investigator was unable to rule out that the events were not related. Given the widespread metastatic tumor and that the measured free MMAE levels were within the range observed in other patients treated at the same dose level, the Investigator could not conclude these events were definitely related to the study drug.

For 1.8mg/kg Q3W, none of the related AEs or SAEs led to treatment discontinuation. For 1.8mg/kg 2Q3W, one (12.5%) of the related AEs or SAEs (multiorgan failure) led to treatment discontinuation.

Overview of adverse events in ozuriftamab vedotin (BA3021) Phase 1 trial for patients administered 1.8mg/kg Q3W (d1) or 2Q3W (d1,8) (safety population)

Characteristic	BA3021 1.8 mg/kg (Q3W) (N=3)	BA3021 1.8 mg/kg (2Q3W) (N=8)
Any AEs	3 (100%)	8 (100%)
Related AEs with CTCAE Grade 3 or 4[1]	1 (33%)	5 (62%)
Any related serious AEs[1]	0	3 (37.5%)
Related AEs leading to death[1]	0	1 (12.5%)
Related AEs leading to treatment discontinuation[1]	0	1 (12.5%)

1. As assessed by the investigator. Missing responses are counted as related.

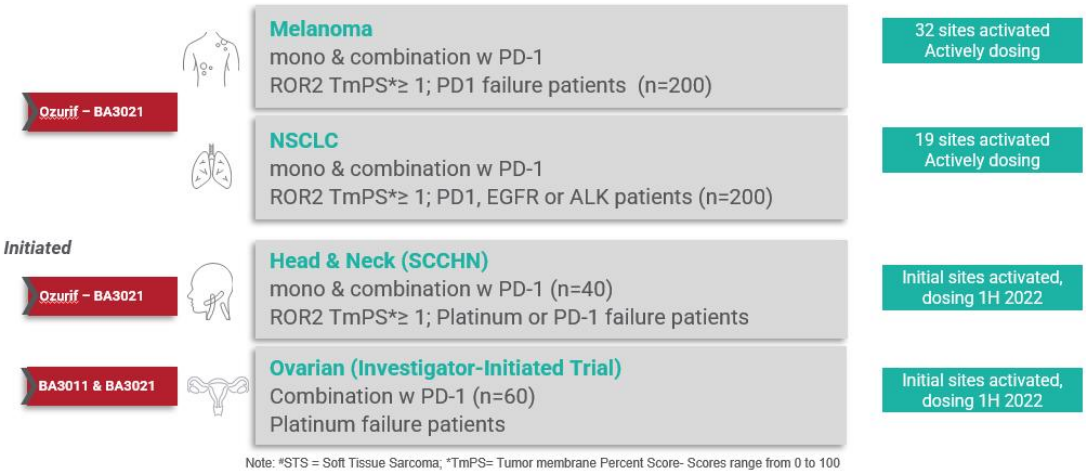
At a dose of 3mg/kg Q3W, two patients experienced dose-limiting toxicities: one with Grade 3 dyspnea (self-resolved without intervention) and the other with Grade 4 febrile neutropenia (in a subject that did not receive prophylactic pegfilgrastim as directed) which resolved on day 2 of hospitalization.

Clinical development plans

We are conducting a potentially registration-enabling Phase 2 trial for ozuriftamab vedotin monotherapy or in combination with a PD-1 inhibitor in melanoma and NSCLC patients that have experienced prior disease progression on a PD1/L1 inhibitor and have a ROR2 TmPS of 1% or more. However, we have not discussed with the FDA whether the Phase 2 clinical trials will be sufficient to support regulatory approval and we cannot assure you that the FDA will agree that such data will be sufficient to support approval. We intend to perform an interim analysis when up to approximately 20 evaluable patients in each indication have the potential to be followed for at least 12 weeks, which we expect to occur in the second half of 2022. Results from these analyses will drive the decision to expand enrollment in each indication to up to 200 patients, and we expect final data in 2024.

We have initiated a Phase 2 clinical trial for ozuriftamab vedotin in head and neck squamous cell carcinoma (SCCHN). In the dose escalation part of the ozuriftamab vedotin Phase 2 trial, we observed a partial response (PR) in one ROR2 positive SCCHN patient (TmPS=16%) who was refractory to four prior lines of therapy including treatment with cetuximab and pembrolizumab. The Phase 2 trial studying SCCHN will enroll 40 patients who had experienced prior failure of PD-1 therapy. Dosing in the first half of 2022, the patients will receive ozuriftamab vedotin monotherapy. Additionally, a multi-center investigator-initiated trial of ozuriftamab vedotin led by CCTG in platinum-resistant ovarian cancer patients has begun enrollment.

Phase 2 clinical development plan for ozuriftamab vedotin (BA3021) for multiple indications



NSCLC and Melanoma Phase 2 trial

This Phase 2 trial is an open-label trial to evaluate the efficacy and safety of ozuriftamab vedotin alone and in combination with an anti-PD-1 agent in patients with ROR2-expressing (TmPS >1%) and metastatic NSCLC or melanoma who have measurable disease by RECIST Version 1.1 criteria and have documented progression according to RECIST v1.1 criteria within the 6 months prior to enrollment.

Enrolled patients are assigned to receive either ozuriftamab vedotin alone or in combination with an anti-PD-1 agent (240 mg every 2 weeks (Q2W)). For the first 20 patients (10 patients in each of the 2 indications) (Part 1), treatment assignment is determined by the sponsor and the medical monitor based on the patient's prior experience with PD-1/L1 treatment. To be eligible for the PD-1 combination arm, patients must have acceptably tolerated prior PD-1/L1 treatment. In Part 2, up to approximately 200 additional patients per indication may be enrolled depending on observed efficacy at interim analysis. For each indication, if both monotherapy and combination therapy are further pursued post interim analysis, patients that have acceptably tolerated prior PD-1/L1 treatment will be randomized 1:1 to receive either ozuriftamab vedotin alone or ozuriftamab vedotin in combination with an anti-PD-1 agent. For the NSCLC indication, randomization will be stratified according to histology (squamous vs. non-squamous) and the number of prior systemic regimens (< 2 vs. < 3). For the melanoma indication, randomization will be stratified according to Eastern Cooperative Oncology Group performance status 0 vs. 1 and the number of prior systemic regimens (< 2 vs. < 3). For both indications, patients that have not acceptably tolerated prior PD-1/L1 treatment will be assigned to the ozuriftamab vedotin monotherapy arm of the study. Based on data from the Phase 1 part of the study, the dose of ozuriftamab vedotin for Phase 2 is 1.8 mg/kg Q2W. A dose reduction to 1.5 mg/kg Q2W may be implemented if deemed warranted by the IDMC.

Tumor assessment will occur approximately every 6 weeks from C1D1 until 12 weeks, and every 8 weeks thereafter. Pharmacokinetic, pharmacodynamic, immunogenicity and biomarker assessments will be performed at various time points.

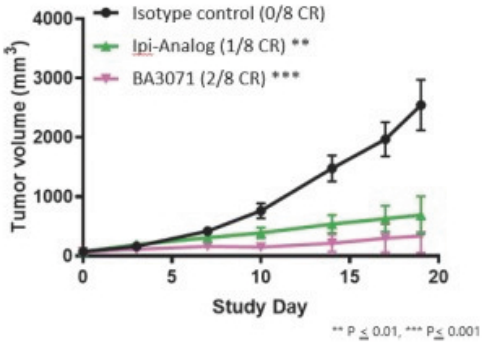
For each indication, an interim analysis will be conducted after up to approximately 20 patients (*e.g.*10 patients in each treatment group) have the potential to be followed for at least 12 weeks after the initiation of investigational product. Following interim analysis, accrual to a treatment (i.e., ozuriftamab vedotin alone or in combination with an anti-PD-1 agent) may be put on hold if the number of patients with a response (i.e., confirmed or unconfirmed complete response or partial response) are below a pre-defined threshold. Depending on observed efficacy at the interim analysis, additional NSCLC and/or melanoma patients may be enrolled for a total of up to approximately 200 patients (100 patients in each of the 2 treatment groups) with ROR2-expressing, metastatic NSCLC and a total of up to approximately 200 patients with ROR2-expressing, metastatic melanoma. The accrual of patients to a treatment regimen(s) (i.e., ozuriftamab vedotin alone and/or ozuriftamab vedotin in combination with an anti-PD-1 agent) can be put on hold by the sponsor at any time based on evaluation of available data or by the IDMC at any time upon review of safety data. Treatment for all enrolled patients will continue until disease progression, unacceptable toxicity or other reason for treatment discontinuation.

BA3071

Preclinical studies

In a mouse colon adenocarcinoma, or MC38, xenograft model in which the human CTLA-4 gene had been introduced, we found that BA3071 had similar antitumor efficacy as a traditional anti-CTLA-4 antibody that is an analog of ipilimumab, or an Ipi-analog. As shown below, BA3071 led to equivalent tumor regression to ipilimumab out of eight treated mice and in two instances we saw a complete response, or no detectable tumor remaining.

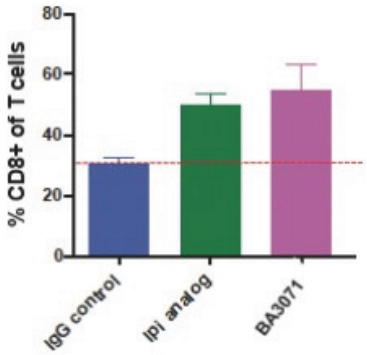
Efficacy in human CTLA-4 engineered mouse model



BA3071 had potent antitumor activity and led to two complete responses in an MC38 tumor cell line model in mice containing the human CTLA-4 gene.

As shown below, examination of the immune cell composition of treated tumors found that those treated with BA3071 antibodies had increased numbers of CD8 T cells than IgG control mice. CD8 T cells are effector cells that mediate tumor cell killing. These levels were similar to those observed in tumors treated with the ipilimumab analog.

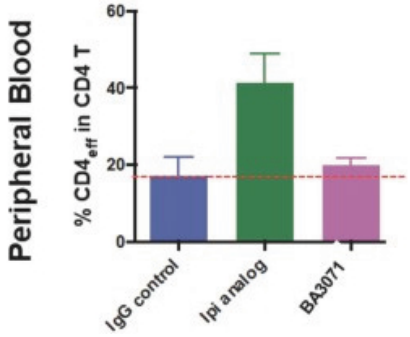
Tumor infiltrating lymphocytes of human CTLA-4 engineered mice



BA3071 functioned similar to ipilimumab in stimulating CD8 T cells in tumors

In contrast, BA3071 antibodies did not lead to changes in the T cell subsets in peripheral blood, as set forth in the figure below. The percentage of CD4 effector cells in CAB-treated mice were similar to those observed with the controls. The percentage of CD4 effector cells in ipilimumab analog-treated mice more than doubled, consistent with systemic inhibition of the CTLA-4 checkpoint. We believe that the observed tumor-restricted activity of BA3071 will be associated with fewer systemic target-based toxicities.

Normal peripheral blood lymphocytes of human CTLA-4 engineered mice

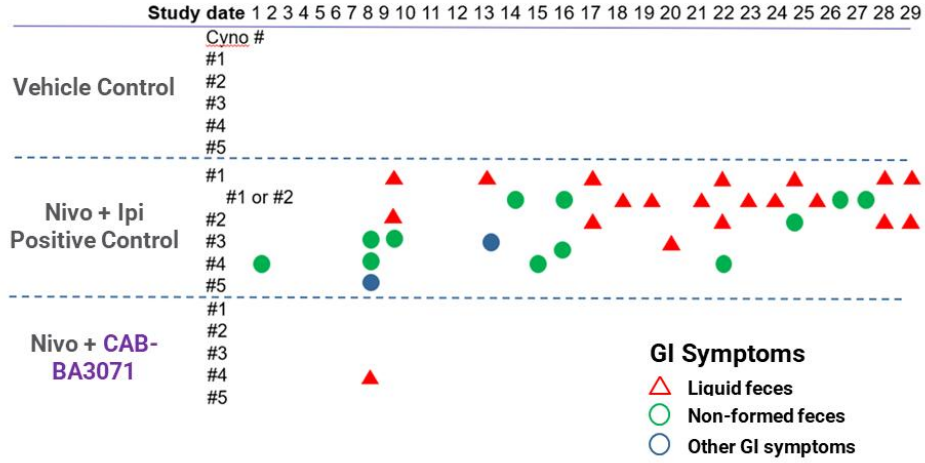


Unlike the ipilimumab analog, BA3071 did not lead to stimulation of T cells in peripheral blood

Safety

Our preclinical toxicity study of BA3071 in non-human primates compares its safety profile to that of ipilimumab. Specifically, as shown in the figure below, we examined the gastrointestinal toxicities associated with combination therapy with nivolumab. To examine toxicities, these animals were dosed with high levels of both agents. Dosing of non-human primates with BA3071 in combination with nivolumab was associated with fewer occurrences of events associated with gastrointestinal toxicity than the combination of ipilimumab and nivolumab. These animals received 20 mg/kg nivolumab, which represents 12 times the human dose, and either 15 mg/kg of ipilimumab or 15 mg/kg of BA3071, which we estimate is 45 to 60 times the current human dose. There were 33 gastrointestinal events such as liquid feces, non-formed feces and other gastrointestinal symptoms in the ipilimumab plus nivolumab combination across 29 days and five animals. There was only a single case of liquid feces in one animal on one day in the BA3071 plus nivolumab treatment group.

Toxicity study of BA3071 comparing its safety profile to ipilimumab



Nivo: 20mg/kg QW (12X human dose); Ipi or CAB-CTLA: 15mg/kg QW (45 – 60X human dose)
Once weekly for four weeks exposure to Nivo + Ipi or CAB CTLA4
AUC_{168} = Area under the serum drug concentration-time curve from time zero to 168 hours; C_{max} = Highest drug concentration observed in serum

Treatment of non-human primates with a combination of BA3071 and nivolumab resulted in fewer gastrointestinal adverse events than treatment with ipilimumab and nivolumab.

These results were consistent with the preclinical results shown two and three figures above that demonstrated that CAB anti-CTLA-4 antibodies had insignificant target-based activity outside of tumors. We believe that this non-human primate study provides support for assessing the safety and tolerability of BA3071 in clinical trials. We anticipate that BA3071 will have a wider therapeutic window than ipilimumab, which may enable it to be better tolerated when used in combination with an anti-PD-1 antibody with the potential to further increase efficacy by allowing administration of higher doses and longer duration of treatment.

Clinical Development Plans

We initiated a Phase 1 dose-escalation trial of BA3071 in advanced solid tumor patients in 2021 and expect our first enrolled patient in the first half of 2022. We expect this trial will examine the safety and tolerability of BA3071 at doses ranging from 7mg Q3W to 700mg Q3W (equivalent to 10mg/kg of ipilimumab) as monotherapy and in combination with an anti-PD-1 antibody.

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. The candidate is in cell line development and a new, highly stable linker was successfully tested in vitro and in vivo.

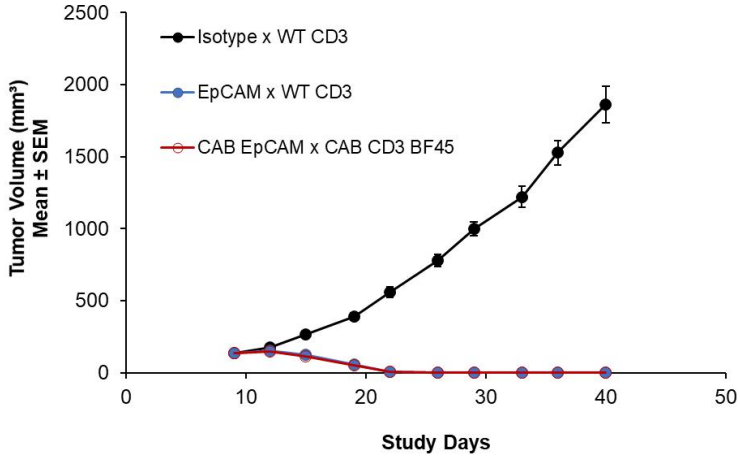
BA3151: CAB-B7-H4-ADC

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.

Bispecific candidates

BA3182: EpCAM x CD3

We have developed and conducted preclinical studies of an EpCAM x CD3 bispecific candidate, BA3182, with an EpCAM binding domain and a CD3 binding domain , both binding domains with CAB activity (Dual-CAB). Dosage was 1mg per kilogram twice per week in mice, which is roughly equivalent to 0.25 mg per kilogram in non-human primates. As shown below, we found this construct had a potent antitumor activity in a HCT116, a human colorectal carcinoma cell line, xenograft model in mice with a humanized immune system.



Safety

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 bispecific antibody in non-human primates.

BA3142: B7-H3 x CD3

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.

BA3311: EGFR x CD3

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. Studies, using a colorectal cancer model to select the clinical lead, are in progress and are expected to be completed in the first quarter of 2022.

Clinical Development Plans

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. Our CAB bispecific antibodies are not expected to lead to systemic immune activation, which we believe 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. We have advanced two CAB bispecific antibody product candidates, BA3182 (EpCAM x CD3) and BA3142 (B7H3 x CD3) into preclinical studies, and BA3311 (EGFR x CD3) is a current subject of IND enabling studies. 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. Our CAB bispecific antibodies are not expected to lead to systemic immune activation, which we believe 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.

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 numerous companies in various stages of clinical development of ADCs, one of the key feature 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 were being developed for the treatment of cancer. Certain other companies are also pursuing antibody therapies in immuno-oncology, such as Seattle Genetics. 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 to maximize the value of our platform and pipeline.

License Agreements

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, BA3071. Under the terms of our BeiGene collaboration, BeiGene was generally responsible for developing the CAB-CTLA-4 antibody and for global regulatory filings and commercialization. Subject to the terms of the agreement, BeiGene held an exclusive license with BioAtla to develop and manufacture the product candidate globally. BeiGene was responsible for all costs of development, manufacturing and commercialization globally. At the time of execution of the BeiGene collaboration, we received a $20 million upfront payment and in December 2019, we received an additional $5 million for the reimbursement of manufacturing costs. We were eligible to receive subsequent development and regulatory milestones globally and commercial milestones in the BeiGene territory, together with tiered royalties on sales worldwide.

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 BA3071, 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 BA3071.

Exclusive License Agreement with Inversagen, LLC

In March 2019, we entered into an Exclusive License Agreement with Inversagen, LLC, as amended in July 2020. Under the terms of the agreement, we granted Inversagen an exclusive, worldwide, royalty-bearing license under certain patents and know-how controlled by us to develop, make, have made, sell, have sold, offer for sale and import CAB-antibodies for the field of diseases associated with aging, outside of cancer, and an immuno-oncology antibody. We may perform development services under the agreement and will be reimbursed by Inversagen for our costs. Commencing on the first commercial sale of the CAB-antibodies and immuno-oncology antibody subject to the agreement, Inversagen will pay us royalties in the mid-single digits, which represents a variable interest held by us. We have an option for a period of 10 years to acquire the sole and exclusive rights solely to develop, make, have made, use, sell, have sold, offer for sale and import the immuno-oncology antibody in the field worldwide (except for the People's Republic of China, Hong Kong, Taiwan and Macau) in return for royalty payments in the low-single digits during the applicable royalty term. For both royalties paid to us by Inversagen and, upon exercise of our option, royalties paid to Inversagen by us, the royalty term, on a product-by-product basis, is the period of time commencing on the first commercial sale of such product in a country and ending upon the later to occur of (i) expiration of the last-to-expire valid claim of the patent rights controlled by us or by Inversagen covering the manufacture, use, sale, offer for sale or import of such product, (ii) 10 years following the first commercial sale of such product in such country and (iii) the expiration of regulatory exclusivity for such product in such country. Unless earlier terminated, the agreement continues in effect so long as Inversagen or any of its affiliates, licensees or sublicensees are developing or commercializing the CAB-antibodies or immuno-oncology antibody in the field or we or any of our affiliates, licensees or sublicensees are developing or commercializing the CAB-antibodies or immuno-oncology antibody outside the field. We can also terminate the agreement with 30 days prior written notice for Inversagen's failure to pay. No payments have been made to date.

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.

Exclusive License Agreement with BioAtla Holdings, LLC

In January 2020, we entered into an Exclusive License Agreement with BioAtla Holdings, LLC, as amended in July 2020. Under the terms of the agreement, we granted BioAtla Holdings an exclusive, worldwide license under certain patents and know-how controlled by us to develop, make, have made, use, sell, have sold, offer for sale and import CAB antibodies for certain targets in the field of Adoptive Cell Therapy, or ACT (CAR-T). Commencing on the first commercial sale of the CAB antibodies subject to the agreement, BioAtla Holdings will pay us royalties in the mid-single digits, which represents a variable interest held by us. We have an option for a period of 10 years to acquire the sole and exclusive rights solely to develop, make, have made, use, sell, have sold, offer for sale and import the ACT preparations and ACT treatments in the ACT field worldwide (except for the People’s Republic of China, Hong Kong, Taiwan and Macau) in return for royalty payments in the low-single digits during the applicable royalty term. For both royalties paid to us by BioAtla Holdings and, upon exercise of our option, royalties paid to BioAtla Holdings by us, the royalty term, on a product-by-product basis, is the period of time commencing on the first commercial sale of such product in a country and ending upon the expiration of the last-to-expire valid claim of the patent rights controlled by us or by BioAtla Holdings covering the manufacture, use, sale, offer for sale or import of such product. We will not owe BioAtla Holdings any milestone or royalty payments unless we exercise our option to acquire the rights to the ACT preparations and ACT treatments. During the term of the agreement, we agreed not to develop, make, have made, use, sell, have sold, offer for sale or import any CAB ACT treatment in the field of ACT. Unless earlier terminated, the agreement continues in effect so long as BioAtla Holdings or any of its affiliates, licensees or sublicensees are developing or commercializing the ACT preparations and treatments in the ACT field or we or any of our affiliates, licensees or sublicensees are developing or commercializing any CAB non-ACT product for any indication outside the ACT field. The agreement may be terminated only by the mutual written agreement of the parties. No payments have been made to date.

In addition, effective January 2020, we entered into a Royalty Sharing Agreement whereby we agreed to share with BioAtla Holdings 50% of the royalties we receive under the license agreement with EXUMA Biotech Corp. (formerly F1 Oncology, Inc.) described below.

Amended and Restated Exclusive License Agreement with EXUMA Biotech Corp

In May 2016, we entered into an Exclusive License Agreement with EXUMA Biotech Corp. (“EXUMA”, formerly F1 Oncology, Inc.) and its affiliates, which, as amended in July 2016 and November 2017 and as amended and restated in November 2019, granted an exclusive, worldwide, sublicensable license under certain patents and know-how controlled by us to develop, manufacture and commercialize four CAB ACT (CAR-T) preparations and treatments for cancer. EXUMA granted us an exclusive, worldwide, royalty free, fully paid-up, sublicensable license under certain patents and know-how controlled by EXUMA and EXUMA’s interest in technology jointly developed under the agreement to develop, manufacture and commercialize non-ACT CAB products for any indication.

EXUMA is obligated to pay us during the royalty term, on a product-by-product basis and country-by-country basis, mid-single-digit royalties based on annual net sales of certain EXUMA ACT products, subject to certain adjustments. The term during which EXUMA is obligated to pay royalties under the agreement with respect to any particular product in any particular country, will begin on the first commercial sale of such product in such country and will end on the date of expiration of the last-to-expire of certain product-related patent rights in such country.

Unless earlier terminated, the agreement continues in effect so long as EXUMA or any of its affiliates, licensees or sublicensees are developing or commercializing any EXUMA products in the ACT field or we or any of our affiliates, licensees or sublicensees are developing or commercializing any CAB products for any indication outside the ACT field. The agreement may be terminated only by the mutual written agreement of the parties.

In connection with the agreement, we received common and preferred stock of EXUMA. These holdings of EXUMA common and preferred stock were retained by BioAtla Holdings in connection with the LLC Division.

In November 22, 2019, we entered into an Amended and Restated Exclusive License Agreement with EXUMA, which curtailed the rights to certain CAB intellectual property previously licensed to EXUMA in exchange for a one-time, non-refundable, non-creditable license fee of $10,000, but does not change EXUMA's obligation to pay us royalties on licensed products. In connection with the Amended and Restated Exclusive License Agreement, BioAtla Holdings sold its EXUMA common and preferred holdings back to EXUMA for consideration of $25,000.

CHO-S Cell Line License Agreement with Life Technologies Corporation

On June 28, 2018, we entered into the CHO-S Cell Line License Agreement with Life Technologies Corporation. Under the terms of the agreement, Life Technologies Corporation provides and grants to us a worldwide, non-exclusive, royalty-free, non-sublicensable license to use certain CHO-S cells to make, or have made, recombinant proteins for clinical or commercial purposes and to seek regulatory approval for the sale of such recombinant proteins in exchange for a one-time, non-refundable, non-creditable license fee of $400,000. No royalties are due by us to Life Technologies Corporation under the agreement. Additional specific lots of Life Technologies Corporation's recombinant proteins may be ordered by us for an additional fee of $50,000 per lot. The term of the agreement continues in perpetuity unless terminated by either party.

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 December 31, 2021, we had 584 patents and patent applications with 319 issued, 8 allowed applications and 257 pending applications.

The objectives of our IP strategy are to increase shareholder value by adequately protecting our platform technologies and compositions of matter, discerning and maximizing the value of our patent portfolio, providing a flexible portfolio that is aligned with our business model and maintaining a cost-effective strategy. We achieve these goals by creating a defensible patent shield, employing most-likely-to-succeed strategies, patenting strategically to reinforce the value of our IP and to minimize costs related to patenting while maximizing value, and by understanding the technology landscape to ensure patentability and freedom to operate. For our CAB products, we act strategically to maximize patent term by timely filing our patent 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 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 the 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 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 153 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. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for future the national/regional patent applications in foreign countries prior to having to incur the filing and translation costs for such applications. 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 153 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.

For all patent applications, we determine the claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications or uses we discover for existing technologies and products, assuming these are strategically valuable. 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 are attentive to the need to avoid the unauthorized use of patented technology belonging to third parties. We 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 prospectus, 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. National phase applications have been granted in Australia, Israel, Japan, 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. National phase applications are pending in 14 jurisdictions in addition to the United States, including most major market countries. Composition of matter claims issuing from this application would not expire before 2037.

BA3071 is covered by a number of filings, including a published PCT application filed in 2019 that entered the national phase in 2021. In addition to filings made in the non-PCT countries of Argentina and Taiwan, national phase applications are pending in 15 jurisdictions in addition to the United States, including most major market countries. Composition of matter claims issuing from this application would not expire before 2039.

Our pre-clinical stage CAB antibody programs, including CAB-anti-EpCAM antibodies and CAB-anti-Nectin-4 antibodies, are covered by a number of filings. As of December 31, 2021, CAB-anti-EpCAM antibodies are covered by 10 national phase filings, including the United States, and a non-PCT filing in Taiwan. CAB-anti-Nectin-4 antibodies are covered by a PCT application 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 15 issued U.S. patents covering various aspects of the manufacturing methods used to generate CAB antibodies that have patent terms expiring from 2030 to 2036. We also have an issued patent in the U.S. protecting our method of manufacturing conditionally active multi-specific antibodies that has a patent term expiring in 2033.

Out-licensed patents

Himalaya Therapeutics SEZC has exclusive rights to patents/patent applications in China, Macao, Hong Kong and Taiwan relating to ROR2 (Patent applications 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 ACT (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 adoptive cell therapy (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 govern, among other things, the testing, manufacturing, safety, purity, potency, labeling, packaging, storage, record keeping, distribution, post-approval monitoring and reporting, 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 Biologic License Application, or 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, 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* 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 for specific targeted diseases 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 provide statistically significant evidence of clinical efficacy and to further test for 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 adverse events 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.

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 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. The PDUFA also imposes an annual prescription drug program. 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 submission to determine if it is substantially complete before the agency files. 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 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 in 10 months after the FDA files the BLA, and priority BLAs in 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 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 for which there is no effective treatment 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 measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. 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 a sponsor's agreement to conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. 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.

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.

Orphan drug designation qualifies a company for tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA.

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. A product becomes an orphan when it receives orphan drug designation from the Office of Orphan Products Development at the FDA 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 on its own 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 product 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 product 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 exclusivity. Competitors may receive approval of either a different product for the same indication or the same product 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. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product 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 product 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 product 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, 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.

Under the FDCA, in vitro diagnostics, including companion 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, approval. 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 biologic 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 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.

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 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, animal studies 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 a finding of interchangeability for other biologics for the same condition of use for the lesser 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 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 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 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.

Brexit and the regulatory framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020. The transition period ended on December 31, 2020. On December 30, 2020, the United Kingdom and EU signed the Trade and Cooperation Agreement (TCA), which includes an agreement on free trade between the two parties. The TCA does not contain wholesale mutual recognition of regulatory regimes for pharmaceuticals as was hoped. There is mutual recognition of cGMP inspections of manufacturing facilities but it does not include reciprocal arrangements for the recognition of batch testing certification, in order to avoid unnecessary re-testing on importation of products.

There is considerable uncertainty resulting from a lack of precedent and the complexity of the United Kingdom and the EU's intertwined legal regimes as to how Brexit will impact the life sciences industry in Europe, including our company, including with respect to ongoing or future clinical trials. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for any product candidates we may develop, which could significantly and materially harm our business. See "Risk factors—Risks related to regulatory approval and other legal compliance matters— 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" for additional disclosures regarding risks related to privacy laws in the United Kingdom and European Union.

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, 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. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. 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. Many of the CPRA's provisions will become effective on January 1, 2023. 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.

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. On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The HHS plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. Many similar proposals, including the plans to give Medicare Part D authority to negotiate drug prices, require drug manufacturers to pay rebates on drugs whose prices increase greater than the rate of inflation, and cap out-of-pocket costs, have already been included in policy statements and legislation currently being considered by Congress. It is unclear to what extent these and other statutory, regulatory, and administrative initiatives will be enacted and implemented.

Human Capital Management

Employees. As of December 31, 2021, we employed 56 employees. We also engaged 18 independent contractors located in China as of December 31, 2021 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, paid time off, paid parental leave, participation in our Employee Stock Purchase Plan and a 401(k) plan.

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 three 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, 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 was founded in March 2007 and originally operated as a Delaware limited liability company, BioAtla, LLC. In July 2020, we converted from a limited liability company into a Delaware corporation pursuant to a statutory conversion and changed our name from BioAtla, LLC 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, including the COVID-19 pandemic, 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 and ozuriftamab vedotin, 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 $95.4 million, $35.9 million, and $29.8 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, we had an accumulated deficit of $186.3 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 increase substantially as we conduct clinical trials of our lead product candidates and seek to expand our pipeline.

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 expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for mecbotamab vedotin, ozuriftamab vedotin and BA3071 and advance our other programs. 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, 2021, we had approximately $245.0 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 into the first half of 2024. 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 and ozuriftamab vedotin;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the clinical development efforts for BA3071;
- the progress of our current and future collaborators with whom we have entered or may in the future enter into collaborations and research and development agreements;
- the timing and amount of target specific indication and 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. 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 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.

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 and ozuriftamab vedotin, and we expect Phase 1 trials of BA3071 first patient dosed in the first half of 2022 and various other product candidates 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. In addition, the FDA may not agree with our clinical trial plans. For example, we have initiated potentially registration-enabling Phase 2 trials for mecbotamab vedotin in treatment-refractory sarcoma patients and PD-1 refractory NSCLC patients. The FDA has reviewed the trial designs but has not opined on whether the Phase 2 clinical trials will in fact be sufficient to support regulatory approval. However, we intend to ask the FDA to consider this further at the planned interim data review point or points. We cannot assure you that the FDA will agree that such data will be sufficient to support approval. 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:

- delays in our clinical trials resulting from factors including those related to the COVID-19 pandemic;
- 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.

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 would 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 and ozuriftamab vedotin, 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. 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, ovarian cancer, 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. In addition, the subset of patients that are likely to respond to our product candidates, as identified by our quantitative biomarker assay/Target Membrane Percent Score ("TmPS"), may not correspond with and may be smaller than what market data may indicate. 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 biopsies to determine the TmPS score for treatment eligibility;
- 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.

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, including in our Phase 2 clinical trials of mecbotamab vedotin for the treatment of soft tissue and bone sarcoma and for the treatment of PD-1 refractory NSCLC, in our Phase 2 clinical trial of ozuriftamab vedotin for the treatment of PD-1 refractory melanoma and NSCLC and 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. For example, we have initiated potentially registration-enabling Phase 2 trials for BA3011 in treatment-refractory sarcoma patients and PD-1 refractory NSCLC. The FDA has reviewed the trial designs but has not opined on whether the Phase 2 clinical trials will in fact be sufficient to support regulatory approval. However, we intend to ask the FDA to consider this further at the planned interim data review point or points. We cannot assure you that the FDA will agree that such data will be sufficient to support approval. 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, while multi-center investigator-initiated clinical trials of mecbotamab vedotin and ozuriftamab vedotin in patients with platinum-resistant ovarian cancer are expected to enroll patients in Canada in the first half of 2022, 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 this 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.

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 late, 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 acceptable product candidate for use in clinical trials in a timely manner, or at all; or
- the COVID-19 pandemic, which continues to adversely affect the pace of patient enrollment in clinical trials, also has caused clinical sites to redirect personnel and resources to focus on immediate and often unplanned numbers and needs of COVID-19 patients. In addition, the pandemic may result in clinical site closures, 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. For example, we may face difficulty enrolling a sufficient number of patients in a timely manner in our clinical trials for mecbotamab vedotin and ozuriftamab vedotin due to the limited number of suitable patients meeting the required AXL or ROR2 tumor membrane expression levels.

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 the COVID-19 pandemic or other 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, negative 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 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.

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 and ozuriftamab vedotin 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 and ozuriftamab vedotin 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 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 and ozuriftamab vedotin in combination with an anti-PD-1 inhibitor and plan to evaluate the use of BA3071 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. It is expected that BA3071 will also be evaluated in combination with an anti-PD-1 antibody in late stage development for solid tumor patients. 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 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.

We are exploring predictive biomarkers to determine patient selection for our clinical trials. Specifically, to help inform which patients may be most suitable for treatment with mecbotamab vedotin and ozuriftamab vedotin, we have developed a quantitative biomarker assay that has been validated in accordance with CLIA requirements, the TmPS, which measures AXL and ROR2 expression levels on the tumor membrane and cytoplasm. We are using both AXL and ROR2 TmPS scores in our ongoing clinical trials and they may be used for patient selection in future

clinical trials. If the AXL and ROR2 TmPS scores prove to be a useful method for patient selection, we will incorporate the specific diagnostic test into our registrational studies and partner with the appropriate diagnostic provider to codevelop a companion diagnostic.

If use of a companion diagnostic test is 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 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. 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 our business, financial condition, results of operations and prospects.

We expect to rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that require such tests. 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 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.

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 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 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 ozuriftamab 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 therapeutic benefit 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, post-marketing confirmatory trials are required to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. 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 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. 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.

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 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. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. 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, 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 European Union 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 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, including 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 April 15, 2021, the FDA issued a 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 an in-person inspection would not be prioritized, deemed mission-critical or is otherwise limited by travel restrictions but where the FDA determines that a remote evaluation would

still be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic.

Additionally, as of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. On July 16, 2020, the FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. 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.

For example, in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both the government and private insurers and significantly impacted the U.S. pharmaceutical industry. Among other things, the ACA 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. By way of example, the ACA increased manufacturers' rebate liability under the Medicaid Drug Rebate Program, imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole," which is now 70% of the negotiated price. There have been executive, legislative and judicial efforts to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. For example, the Tax Cuts and Jobs Act, among other things, included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural

grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how the any future challenges to the ACA and the healthcare reform measures of the Biden administration will impact the ACA and our business. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, and a reduction to the sequestration cut to 1% from April 1, 2022 to June 30, 2022, due to the COVID-19 pandemic. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations. 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.

Furthermore, on September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The HHS plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. Many similar proposals, including the plans to give Medicare Part D authority to negotiate drug prices, require drug manufacturers to pay rebates on drugs whose prices increase greater than the rate of inflation, and cap out-of-pocket costs, have already been included in policy statements and legislation currently being considered by Congress. It is unclear to what extent these and 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 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.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

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. 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. It is possible that additional governmental action is taken to address the COVID-19 pandemic. For example, on April 18, 2020, CMS announced that QHP issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to the COVID-19 virus.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology 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 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.

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 state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

State and foreign 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 European Union is governed by the General Data Protection Regulation, or the GDPR, which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions, tightens existing European Union 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, on June 28, 2018, the State of California enacted the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020. The CCPA 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. Additionally, although not effective until January 1, 2023, the CPRA, which expands upon the CCPA, was passed in the November 2020 election. The CCPA has created new individual privacy rights and places increased privacy and security obligations on entities handling personal information. The CPRA 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 may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations 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 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. 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 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 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 and Scott Smith, our President, as well as our 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, 2021, we had 56 employees, and 18 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:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory review process for mecbotamab vedotin and ozuriftamab vedotin 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 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 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 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 engage in misconduct or other illegal activity. Misconduct by these parties 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) federal and state 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 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. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business 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.

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 of or destruction of our proprietary and confidential data, employee data or personal data, which could result in additional costs, significant liabilities, harm to our reputation and material disruption of our operations.

Despite the implementation of security measures, our internal computer systems 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 damage from various methods, including cybersecurity attacks, breaches, intentional or accidental mistakes or errors, or other technological failures, which can include, among other things, computer viruses, 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, sophistication and intensity, and are becoming increasingly difficult to detect. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy 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. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable 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. 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 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.

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. 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. 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 which are stored in a one master cell bank for each antibody manufactured stored in multiple locations. 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 European Union, Australia, New Zealand, and Japan. We conduct preclinical research and development activities in China through BioDuro-Sundia, which is U.S. owned, but governed by Chinese laws. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- 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.

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 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.

We face risks related to health epidemics or outbreaks of communicable diseases. For example, in December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, emerged in China. Since then, COVID-19 has spread to multiple countries worldwide, including the United States and member states of the European Union. On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a pandemic. The outbreak of such 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. The COVID-19 pandemic has resulted 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. For example, our primary operations are located in San Diego, California, and San Diego County and the State of California had issued shelter-in-place orders in response to the COVID-19 pandemic. Although some restrictions aimed at minimizing the spread of COVID-19 have been and may from time to time be eased or lifted in the U.S. and other countries, in response to local surges and new waves of infection, including those caused by the spread of the Delta, Omicron and other variants, some countries, states, and local governments have maintained or reinstituted these restrictions, or may reinstitute these restrictions from time to time, in response to rising rates of infection.

We are following, and plan to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. In March 2020, we implemented a remote working policy for many of our employees and began restricting non-essential travel. 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 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 is having a severe effect on the clinical trials of many drug candidates of several sponsors. Some trials have been merely delayed, while others have been cancelled. The extent to which the COVID-19 pandemic may impact our preclinical and clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration and geographic reach of the outbreak, the severity of COVID-19 (including its variant strains, such as the highly transmissible Delta and Omicron variants), the effectiveness of actions to contain and treat COVID-19 and the rate of vaccination and efficacy of approved vaccines against COVID-19 and its variant strains. 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. The continued spread of COVID-19 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 the 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 may in the future seek third-party collaborators or joint venture partners for development and commercialization of additional 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. We currently rely on third parties to manage and conduct our clinical trials of mecbotamab vedotin and ozuriftamab vedotin. 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. 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.

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. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects. 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 which are stored in a cell bank. We have one master cell bank for each antibody manufactured in accordance with cGMPs, which is stored in multiple locations. We are currently creating multiple working cell banks. 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 the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects. 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. As of March 24, 2021, there is an ongoing patent opposition proceeding regarding our patent EP2 406 399 at the European Patent Office which is related to a version of methods used for evolving and screening potential product candidates. The Opposition Division revoked EP2 406 399 in its decision dated March 10, 2020 and we filed an appeal on July 20, 2020. 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 2037, 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 2041 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 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, weakening the rights of patent owners 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:

- 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 analyst 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.

The dual class structure of our common stock and the option of the holder of shares of our Class B common stock to convert into shares of our common stock may limit your ability to influence corporate matters.

Our common stock has one vote per share, while our Class B common stock is non-voting. Nonetheless, each share of our Class B common stock may be converted at any time into one share of common stock at the option of its holder, subject to the limitations provided for in our amended and restated certificate of incorporation. Consequently, if holders of Class B common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our Class B common stock, and correspondingly decrease the voting power of the current holders of our common stock, which may limit your ability to influence corporate matters. Because our Class B common stock is generally non-voting, stockholders who own more than 10% of our Class B common stock and common stock overall but 10% or less of our common stock will not be required to report changes in their ownership from transactions in our Class B common stock pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and would not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act. In addition, acquisitions of Class B common stock would not be subject to notification pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

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, 2021, executive officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially own approximately 29.4% of our outstanding common stock. More specifically, Jay M. Short, Ph.D, our Chairman and Chief Executive Officer, together with his spouse, Carolyn Anderson Short, our former Chief of Intellectual Property and Strategy and Assistant Secretary, owned 6.9%, of our outstanding common stock, as of December 31, 2021.

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 wife, Carolyn Anderson Short, are each a manager of Inversagen, LLC and BioAtla Holdings, LLC and a director of Himalaya Therapeutics SEZC. In addition, Ms. Anderson Short 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.

Certain holders of our outstanding shares have rights, subject to certain conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We also 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 and the lock-up agreements.

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 mandates 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 SEC recently approved new 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 would 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 will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new 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, and particularly after we are no longer an emerging growth company or a smaller reporting company, we will 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 will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or to incur substantial costs to maintain the same or similar coverage. 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 will be required to incur additional 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 we are 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, and will need to continue, to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of 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. In the future, we may need to increase the number of employees dedicated to finance and reporting, or engage outside consultants to meet requirements, which will increase 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 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 February 25, 2022, there were 16 stockholders of record of our common stock and 2 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

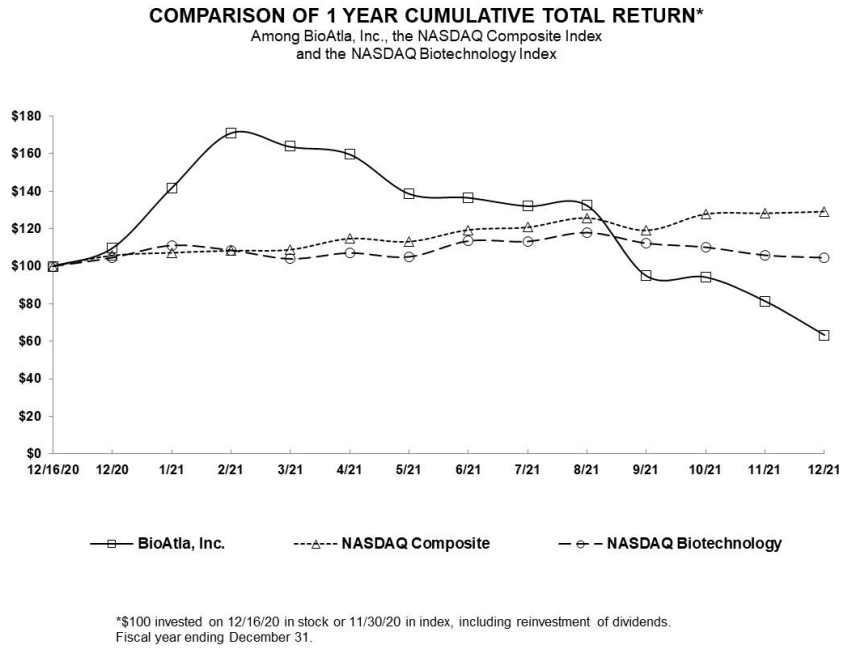
Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Stock Performance Graph

The graph set forth below compares the cumulative total stockholder return on our common stock for the period commencing on December 16, 2020, the date our common stock began trading on the Nasdaq, and ending on December 31, 2021, with the cumulative total return of the Nasdaq Composite Index and the Nasdaq Biotechnology Index over the same period. This graph assumes the investment of $100.00 on December 16, 2020 in each share of our common stock at the initial public offering price of $18.00, the Nasdaq Composite Index, and the Nasdaq Biotechnology Index, and assumes the reinvestment of dividends.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock. Information used in the graph was obtained from sources believed to be reliable including Nasdaq, Bloomberg and Reuters, but we are not responsible for any errors or omissions in such information.

Notwithstanding anything to the contrary set forth in any of our previous or future filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, that might incorporate this Annual Report on Form 10-K or future filings made by us under those statutes, this Stock Performance Graph section is not "soliciting material," shall not be deemed filed with the U.S. Securities and Exchange Commission and shall not be deemed incorporated by reference into any of those prior filings or into any future filings made by us under those statutes.



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 (or "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, 2021, we have used approximately $24.3 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. Selected Financial Data

Not applicable.

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 consolidated 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." The discussion of our financial condition and results of operations for the year ended December 31, 2019, included in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") can be found in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 24, 2021.

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 and ozuriftamab vedotin, 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 do not have any products approved for sale, and we have not generated any revenue from product sales.

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 $95.4 million, $35.9 million, and $29.8 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, we had an accumulated deficit of $186.3 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 increase substantially as we conduct clinical trials of our lead product candidates and seek to expand our pipeline.

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 BA3071;
- 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.

Furthermore, we expect to continue to incur additional costs associated with operating as a public company.

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, 2021, our cash and cash equivalents totaled approximately $245.0 million. Based on our current operating plan, our current cash and cash equivalents are expected to be sufficient to fund our ongoing operations into the first half of 2024. However, 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.

BioAtla was formed in April 2007 as a Delaware limited liability corporation. We initially operated as a service provider and service-related partnered drug developer for primarily human therapeutic proteins and simultaneously refined our proprietary CAB technology platform and related technologies. Since 2013, we transitioned away from our services business to focus on internal development of our own proprietary products.

Impact of COVID-19 on our business

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 caused by a novel strain of coronavirus as a pandemic, which continues to spread throughout the United States and around the world. The worldwide COVID-19 pandemic may affect our ability to complete our current preclinical studies and clinical trials, initiate and complete our planned preclinical studies and clinical trials, disrupt regulatory activities or have other adverse effects on our business, results of operations, financial condition and prospects. In addition, the pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could adversely affect our business, operations and ability to raise funds to support our operations. To date, we have experienced modest business disruptions, including with respect to clinical trials we are conducting, and non-material impairments as a result of the pandemic. Our Phase 2 sarcoma trial remains on schedule and the Phase 2 interim analysis for AXL NSCLC and ROR2 studies have experienced some modest delays in patient initiations due to COVID-19, however, overall timelines for study completion essentially have not changed at this time. We are following, and plan to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. In March 2020, we implemented a remote working policy for many of our employees, began restricting non-essential travel and temporarily reduced salaries of our employees from March 2020 to July 2020. We are complying with all applicable guidelines for our clinical trials, including remote clinical monitoring. In April 2020, we borrowed $0.7 million under the Paycheck Protection Program under the CARES Act and we received full loan forgiveness from the U.S. Small Business Association in July 2021, resulting in the recognition of $0.7 million to other income for the twelve months ended December 31, 2021. The PPP loan is discussed further under "—Liquidity and capital resources." We are continuing to monitor the potential impact of the pandemic, but we cannot be certain what the overall impact will be on our business, financial condition, results of operations and prospects.

Recent developments

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 Conditionally Active Biologic Antibody Drug Conjugates, mecbotamab vedotin and ozuriftamab vedotin, each in combination with Opdivo® (nivolumab), BMS' proprietary anti-PD-1 monoclonal antibody product. We 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, we are obligated to provide BMS with a final report of the data resulting from the trial.

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. In addition to the collaboration agreements discussed below, we may in the future seek third-party collaborators or joint venture partners for development and commercialization of additional CAB product candidates.

In April 2019, we entered into a Global Co-Development and Collaboration Agreement with BeiGene, Ltd. which was amended in December 2019, October 2020, and was terminated in November 2021. The original agreement provided for the development, manufacturing and commercialization of BA3071 in collaboration with BeiGene. After the November 2021 amendment, we are responsible for developing BA3071, including global regulatory filings and commercialization, and are responsible for all costs of development, manufacturing and commercialization globally. At the time of execution of the BeiGene collaboration, we received a $20.0 million upfront payment and in December 2019, we received an additional $5.0 million for the reimbursement of manufacturing costs. Pursuant to the terms of the November 2021 amendment, we agreed to

pay single digit royalties to BeiGene and agreed to share on a limited basis in any upfront and milestone payments received through a sublicense of BA3071.

During 2020, we recognized revenue primarily from our collaboration with BeiGene. During 2019, we recognized revenue from our collaboration with BeiGene and, to a much lesser degree, from our collaboration with Pfizer.

Prior to developing our own programs, the Company received revenue from services performed under fixed price service contracts that, in some cases, provided for potential milestone and royalty payments to us. During 2021, we recognized $0.3 million in revenues from our legacy service contracts.

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, including through our relationship with BioDuro-Sundia, 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, cost of facilities and depreciation expenses.

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 increase substantially for the foreseeable future as we continue to invest in research and development activities to advance our product candidates and our clinical programs and expand our product candidate pipeline. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. 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 consist primarily of 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, 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 increase as a result of operating as a public company, including additional costs (i) to comply with the rules and regulations of the SEC and those of The Nasdaq Global Market, (ii) for legal and auditing services, (iii) for additional insurance, (iv) for investor relations activities and (v) for other administrative and professional services. We also expect our intellectual property expenses to increase as we expand our intellectual property portfolio.

Interest income

Interest income consists primarily of interest earned on our cash and cash equivalent balances. Our interest income has not been significant to date and we do not expect any material changes.

Interest expense

Interest expense consists primarily of interest incurred on our outstanding convertible debt, including coupon interest and the amortization of debt discounts, including those related to beneficial conversion features and embedded derivatives. Our interest expense declined subsequent to the settlement of our outstanding convertible debt in July 2020 and the forgiveness of our PPP loan in July 2021.

Change in fair value of derivative liability

The convertible promissory notes we issued during 2019 and 2020 contained redemption features which we determined were embedded derivatives to be recognized as liabilities and measured at fair value. At the end of each reporting period, changes in the estimated fair value during the period were recorded as a change in the fair value of derivative liability. The embedded derivative liability was recorded at fair value utilizing an income approach that identified the cash flows using a "with-and-without" valuation methodology. The inputs used to determine the estimated fair value of the derivative instrument were based primarily on the probability of an underlying event triggering the embedded derivative occurring and the timing of such event. We will no longer record changes in the fair value of the derivative liability subsequent to the settlement of the derivative liability in connection with the conversion of our outstanding convertible debt in July 2020.

Extinguishment of debt

In April 2020, we amended the terms of certain outstanding convertible promissory notes that we concluded were extinguishments. In July 2020, in connection with our Corporate Reorganization, we settled all of our outstanding convertible promissory notes and recognized extinguishment losses for the difference between the fair value of the consideration given to the noteholders and the carrying value of the related convertible promissory notes. In July 2021, our PPP loan was fully forgiven and we recorded a gain on extinguishment equal to the principal and interest outstanding at the time of forgiveness.

Other income (expense)

Other income (expense) primarily includes miscellaneous items of income and expense that were not significant for the periods presented.

Results of operations

Comparison of the years ended December 31, 2021 and 2020

	Years Ended December 31,		
	2021	2020	Change
	(in thousands)		
Collaboration and other revenue	$ 250	$ 429	$ (179)
Operating expenses:			
Research and development	58,274	19,933	38,341
General and administrative	38,416	10,595	27,821
Total operating expenses	96,690	30,528	66,162
Loss from operations	(96,440)	(30,099)	(66,341)
Other income (expense):			
Interest income	350	100	250
Interest expense	(3)	(1,389)	1,386
Change in fair value of derivative liability	—	(1,581)	1,581
Gain (loss) on extinguishment of long-term debt	690	(2,883)	3,573
Other income (expense)	1	(1)	2
Total other income (expense)	1,038	(5,754)	6,792
Consolidated net loss and comprehensive loss	$ (95,402)	$ (35,853)	$ (59,549)

Collaboration and other revenue

Collaboration and other revenue for the years ended December 31, 2021 and 2020 consisted of $0.3 million recognized under our legacy service contracts, and $0.4 million of revenue recognized under our collaboration with BeiGene, respectively. As part of the November 2021 amendment to the agreement with BeiGene, we reclassified the remaining $19.8 million of deferred revenue as a long-term liability which we expect 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.

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,		
	2021	2020	Change
	(in thousands)		
External expenses:			
BA3011 (AXL-ADC)	$ 17,883	$ 7,845	$ 10,038
BA3021 (ROR2-ADC)	10,921	3,190	7,731
Other CAB Programs	14,954	3,718	11,236
Total external expenses	43,758	14,753	29,005
Personnel and related	6,999	5,120	1,879
Equity-based compensation	4,688	(2,252)	6,940
Facilities and other	2,829	2,312	517
Total research and development expenses	$ 58,274	$ 19,933	$ 38,341

Research and development expenses were $58.3 million and $19.9 million for the years ended December 31, 2021 and 2020, respectively. The increase of $38.3 million was primarily driven by a $17.8 million increase in external costs as due to manufacturing and clinical development for our clinical programs BA3011 and BA3021, a $11.2 million increase in pre-clinical development including manufacturing and IND enabling studies for CAB pipeline programs, a $4.0 million increase in stock-based compensation due to awards issued in connection with our 2020 Equity Incentive Plan, a $3.0 million increase in equity-based compensation related to a decrease in the fair value of awards under our profits interest plan during the year ended December 31, 2020, a $1.9 million increase in personnel related costs due to an increase in headcount to support ongoing development activities for our programs, and $0.5 million increase in facility, depreciation and allocated costs.

General and administrative expense

General and administrative expenses were $38.4 million and $10.6 million for the years ended December 31, 2021 and 2020, respectively. The increase of $27.8 million was primarily driven by a $18.2 million increase in stock-based compensation due to awards issued in connection with our 2020 Equity Incentive Plan and the modification of awards issued to one of our co-founders, a $3.8 million increase in equity-based compensation related to a decrease in the fair value of awards under our profits interest plan during the year ended December 31, 2020, a $2.9 million increase in insurance expense, a $1.5 million increase in personnel related expenses as we expanded our administrative functions in support of our development activities plus severance benefits related to the departure of one of our co-founders, a $1.2 million increase in professional fees related to accounting, audit and legal services, a $0.4 million increase in other expenses including corporate franchise taxes and software subscriptions, and a $0.3 million increase in depreciation expense. These decreases were offset by a $0.4 million decrease in facility and allocated costs.

Interest income

Interest income was $350,000 and $100,000 for the years ended December 31, 2021 and 2020, respectively. The increase of $250,000 was due to higher average cash and cash equivalent balances after our December 2020 IPO and September 2021 private placement.

Interest expense

Interest expense was $3,000 and $1.4 million for the years ended December 31, 2021 and 2020, respectively. The decrease of $1.4 million was due to reduced interest expense as a result of the settlement of all of our convertible debt in July 2020.

Change in fair value of derivative liability

Change in fair value of derivative liability was $0 and $1.6 million for the years ended December 31, 2021 and 2020, respectively. The decrease of $1.6 million was primarily due to changes in the fair value of embedded derivatives issued in connection with our outstanding convertible promissory notes which all settled in July 2020.

Extinguishment of debt

Extinguishment of long-term debt resulted in a $0.7 million gain and a $2.9 million loss on extinguishment during the years ended December 31, 2021 and 2020 related to the forgiveness of our PPP loan in July 2021 and the settlement of our then outstanding convertible promissory notes in connection with our July 2020 Series D Financing, respectively.

Other income (expense)

We had minimal other income and expense for the years ended December 31, 2021 and 2020.

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. As of December 31, 2021, we had cash and cash equivalents of $245.0 million.

Debt

On April 22, 2020, we received proceeds from a loan, or PPP Loan, in the amount of $0.7 million from City National Bank, as lender, pursuant to the Paycheck Protection Program, or PPP, of the CARES Act. In July 2021, we were notified by our lender, City National Bank, that our PPP Loan had been fully forgiven by the SBA and that there was no remaining balance on the PPP Loan. We recorded the forgiveness as other income in 2021.

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 into the first half of 2024. However, 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.

In addition, 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 the COVID-19 pandemic 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,	
	2021	2020
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (62,214)	$ (36,334)
Investing activities	(924)	(590)
Financing activities	69,512	271,825
Net increase in cash and cash equivalents	$ 6,374	$ 234,901

Cash used in operating activities

Net cash used in operating activities for the year ended December 31, 2021 was $62.2 million, which consisted of a consolidated net loss of $95.4 million, a net increase of $7.4 million in our net operating assets and liabilities and $25.8 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 $8.0 million, a decrease in prepaid expenses and other assets of $0.2 million, offset by a net increase in operating lease right-of-use assets and liabilities of $0.3 million in conjunction with the adoption of ASC 842. The non-cash transactions primarily consisted of $25.1 million of stock-based compensation and non-cash charges of $1.3 million related to depreciation and amortization, offset by the $0.7 million gain on the extinguishment of our PPP loan.

Net cash used in operating activities for the year ended December 31, 2020 was $36.3 million, which consisted of a consolidated net loss of $35.9 million, a net change of $2.5 million in our net operating assets and liabilities and $2.0 million of non-cash transactions. The net change in our operating assets and liabilities was primarily due to a decrease in accounts payable and accrued expenses of $1.7 million, an increase in prepaid expenses and other assets of $1.3 million, an increase in accrued interest of $0.9 million on our outstanding convertible debt prior to its settlement in July 2020, and a decrease in deferred revenue of $0.4 million as we recognized deferred revenue related to our collaboration with BeiGene. The non-cash transactions primarily consisted of $3.0 million of stock-based compensation related to the issuance of RSUs and stock options in the fourth quarter of 2020, a $2.9 million loss on extinguishment of convertible debt, a $1.6 million change in the fair value of our derivative liability, non-cash charges of $1.0 million related to depreciation and amortization and $0.5 million of non-cash interest, offset by a decrease in the fair value of our profits interest liability and pushdown from our affiliate of $6.9 million and $0.2 million of deferred rent.

Cash used in investing activities

Cash used in investing activities was $0.9 million and $0.6 million for the years ended December 31, 2021 and 2020, respectively, related to the purchase of property and equipment.

Cash provided by financing activities

Net cash provided by financing activities was $69.5 million for the year ended December 31, 2021, which consisted primarily of the net proceeds from the issuance of common stock through a Private Placement of $71.0 million, the proceeds from the issuance of common stock under our Employee Stock Purchase Plan of $0.3 million, and $0.1 million due to the exercise of stock options under our Equity Incentive Plan, partially offset by our payment of initial public offering costs of $1.9 million.

Net cash provided by financing activities was $271.8 million for the year ended December 31, 2020, which consisted of $200.2 million of net proceeds from our initial public offering, $68.2 million of net proceeds from our issuance of Series D convertible preferred stock, $2.8 million of proceeds from the issuance of convertible promissory notes and $0.7 million of proceeds from our PPP loan.

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 consolidated 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 consolidated 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.

Collaboration revenue

We recognize 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 we are entitled to receive in exchange for such product or service. In doing so, we follow 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. We consider 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 us, where the purpose of the contract is to obtain a product or a service that is an output of our 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 we will collect substantially all of the consideration to which we are 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. We identify 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) our 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 we are entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, we consider the existence of any significant financing component, the effects of any variable elements, noncash considerations 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, we 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, we allocate the transaction price to each distinct performance obligation in an amount that reflects the consideration we are entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) we transfer control of the product or the service applicable to such performance obligation.

In those instances where we first receive consideration in advance of satisfying our performance obligation, we classify such consideration as deferred revenue until (or as) we satisfy such performance obligation. In those instances where we first satisfy our performance obligation prior to receipt of consideration, the consideration is recorded as accounts receivable.

We expense 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.

Profits interest liability

Before the Corporate Reorganization, we had a profits interest plan which we determined was a liability award plan in accordance with authoritative guidance. We measured the fair value of each award on the grant date and recognized such fair value over the requisite service period (usually the vesting period) on a straight-line basis, net of estimated forfeitures. The fair value of the award was remeasured at each reporting date until the award was settled, with a true-up of compensation cost for changes in fair value prorated for the portion of the requisite service period rendered. Once vested, any subsequent change in fair value was recognized immediately. The fair value of any awards that expired or were forfeited or cancelled for no value was adjusted to zero, such that any previously recorded compensation cost was fully reversed.

We were required to estimate the fair value of the Class B units issued in connection with our profits interest plan. The fair value of our Class B units was determined on each reporting date by our management, taking into account input from independent third-party valuation analysis. In the absence of a public trading market for our Class B units, on each reporting date we developed an estimate of the fair value of our Class B units in order to calculate the profit interest liability. Our determinations of the fair value of our Class B units were made using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants *Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation*, or the Practice Aid.

We considered various objective and subjective factors to determine the fair value of our Class B units, including:

- contemporaneous valuations of our Class B units performed by independent third-party valuation specialists;
- our stage of development and business strategy, including the status of research and development efforts of our product candidates, and the material risks related to our business and industry;
- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly traded companies in the life sciences and biopharmaceutical sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of liquidity of our Class B units;
- the rights, preferences and privileges of our Class C Preferred units and Class A units relative to those of our Class B units;
- the likelihood and timing of achieving a liquidity event for the holders of our Class B units, given prevailing market conditions;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biopharmaceutical industry sectors.

Valuation methodologies and methods used to allocate our enterprise value to classes of securities

Our valuations were prepared in accordance with the guidelines in the Practice Aid, which prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our company's future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics. Each valuation methodology was considered in our valuations. We utilized a market approach in 2019 and 2020. In 2020, in connection with our Corporate Reorganization and Series D preferred stock financing, our market approach included the back-solve method that assigns an implied enterprise value based on the most recent round of funding or investment and allows for the incorporation of the implied future benefits and risks of the investment decision assigned by an outside investor. In accordance with the Practice Aid, we considered the various methods for allocating the enterprise value across our classes and series of equity to determine the fair value of our equity instruments at each valuation date. We applied a hybrid method of the probability weighted expected return method, or PWERM, where the non-IPO scenario is modeled using an option pricing model to reflect the full distribution of possible non-IPO outcomes. Under the option pricing model, units are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of each class of units are inferred by analyzing these options. In the IPO scenario, we used the fully-diluted shares outstanding to allocate value to each class of units. The hybrid method is useful when certain discrete future outcomes can be predicted, but also accounts for uncertainty regarding the timing or likelihood of specific alternative exit events.

Stock-based compensation

In October 2020 we adopted our 2020 Equity Incentive Plan and began to grant stock options and RSUs and began to recognize stock-based compensation expense in the fourth quarter of 2020.

Stock-based compensation expense represents the grant date fair value of equity awards recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of stock option grants using the Black-Scholes option pricing model and the fair value of RSUs is the fair value of our common stock on the date of grant. See Note 7 to our consolidated financial statements included elsewhere in this Annual Report for information concerning the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock option grants. The fair value of our common stock for awards granted under our equity incentive plan will be based on the closing price as reported on the date of the grant on the primary stock exchange on which our common stock is traded. Equity award forfeitures are recognized as they occur.

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

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. We had cash, cash equivalents and short-term investments of $245.0 million and $238.6 million as of December 31, 2021 and 2020, respectively, which consisted of bank deposits and money market funds. Such interest-bearing instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant.

We do not enter into investments for trading or speculative purposes and we do not currently utilize derivative financial instruments to manage our interest rate exposure. We have not historically been exposed to material risks due to changes in interest rates.

Foreign Currency Exchange Risk

Our contracts with customers are primarily denominated in U.S. dollars, with a small amount denominated in foreign currencies. As such, fluctuations in foreign currency exchange rates may cause us to recognize transaction gains and losses in our statement of operations. To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements, and we have not engaged in any foreign currency hedging transactions.

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 consolidated balance sheets of BioAtla, Inc. (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders'/members' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 28, 2022 expressed an unqualified opinion thereon.

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 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. 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 consolidated 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 2021, the Company incurred $58.3 million for research and development expenses and as of December 31, 2021 accrued $6.2 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	We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the accounting for accrued clinical trial expenses. For example, we tested controls over management's assessment and measurement of estimated accrued clinical trial costs, including patient enrollment and total costs billed but unpaid as of year end. 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 understand the status of significant clinical trial activities. 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
February 28, 2022

BioAtla, Inc.
Consolidated balance sheets
(in thousands, except share/unit amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 244,979	$ 238,605
Prepaid expenses and other current assets	2,313	2,076
Total current assets	247,292	240,681
Property and equipment, net	3,676	4,102
Operating lease right-of-use-asset, net	3,300	—
Other assets	154	154
Total assets	$ 254,422	$ 244,937
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 18,424	$ 12,068
Current portion of deferred rent	—	387
Current portion of deferred revenue	—	19,806
Operating lease liabilities	1,389	—
Total current liabilities	19,813	32,261
Long-term accrued interest	—	5
Deferred rent, less current portion	—	2,015
Operating lease liabilities, less current portion	3,982	—
Liability to licensor	19,806	—
Other debt	—	682
Total liabilities	43,601	34,963
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 200,000,000 shares authorized at December 31, 2021 and 2020; 0 shares issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, $0.0001 par value; 350,000,000 authorized at December 31, 2021 and 2020; 35,799,233 shares and 32,171,560 shares issued and outstanding at December 31, 2021 and 2020	4	3
Class B common stock, $0.0001 par value; 15,368,569 shares authorized at December 31, 2021 and 2020; 1,492,059 shares issued and outstanding at December 31, 2021 and 2020	—	—
Additional paid-in capital	397,136	300,888
Accumulated deficit	(186,319)	(90,917)
Total stockholders' equity	210,821	209,974
Total liabilities and stockholders' equity	$ 254,422	$ 244,937

See accompanying notes.

BioAtla, Inc.
Consolidated statements of operations and comprehensive loss
(in thousands, except share/unit and per share/unit amounts)

	Years ended December 31,		
	2021	2020	2019
Collaboration and other revenue	$ 250	$ 429	$ 5,200
Operating expenses:			
Research and development expense (includes related party amounts of $0, $0, and $1,885, respectively)	58,274	19,933	25,919
General and administrative expense (includes related party amounts of $0, $0, and $15, respectively)	38,416	10,595	7,549
Total operating expenses	96,690	30,528	33,468
Loss from operations	(96,440)	(30,099)	(28,268)
Other income (expense):			
Interest income	350	100	128
Interest expense (includes related party amounts of $0, $147 and $52, respectively)	(3)	(1,389)	(1,630)
Change in fair value of derivative liability	—	(1,581)	(63)
Gain (loss) on extinguishment of long-term debt	690	(2,883)	—
Other income (expense)	1	(1)	(22)
Total other income (expense)	1,038	(5,754)	(1,587)
Consolidated net loss and comprehensive loss	(95,402)	(35,853)	(29,855)
Net loss attributable to noncontrolling interests	—	—	61
Net loss attributable to BioAtla, Inc./BioAtla LLC	$ (95,402)	$ (35,853)	(29,794)
Net loss allocable to Class C preferred unit holders			9,089
Class C preferred return			(8,026)
Net loss attributable to Class A unit holders			$ (28,731)
Net loss per unit attributable to Class A unit holders, basic and diluted			$ (0.53)
Weighted-average Class A units outstanding, basic and diluted			54,600,000
Net loss per common share, basic and diluted (1)	$ (2.76)	$ (3.19)	
Weighted-average shares of common stock outstanding, basic and diluted (1)	34,561,245	8,428,153	

(1) The net loss attributable to common stockholders and related per share amounts for the year ended December 31, 2020 are based on the period from July 10, 2020 to December 31, 2020, the period where the Company had outstanding common stock (see Note 1).

See accompanying notes.

BioAtla, Inc.
Consolidated statements of convertible preferred stock and stockholders'/members' equity (deficit)
(in thousands, except share/unit amounts)

	Series D convertible preferred stock		Class C preferred units		Class A units		Common stock		Class B common stock		Additional paid-in	Accumulated	Non-controlling	Total stockholders' / members' equity
	Shares	Amount	Units	Amount	Units	Amount	Shares	Amount	Shares	Amount	capital	deficit	interest	(deficit)
Balance at Ended December 31, 2018	—	$ —	23,968,178	$ 89,345	54,600,000	$ 750	—	$ —	—	$ —	$ —	$ (118,560)	$ 19	$ (28,446)
Noncontrolling interest	—	—	—	—	—	—	—	—	—	—	—	—	(5)	(5)
Warrants issued by affiliates in connection with modification of convertible promissory notes	—	—	—	—	—	—	—	—	—	—	764	—	—	764
Assumption of unvested profits interest liability by affiliates	—	—	—	—	—	—	—	—	—	—	197	—	—	197
Assumption of vested profits interest liability by affiliates	—	—	—	—	—	—	—	—	—	—	800	—	—	800
Beneficial conversion feature in convertible promissory notes	—	—	—	—	—	—	—	—	—	—	534	—	—	534
Net loss	—	—	—	—	—	—	—	—	—	—	—	(29,794)	(61)	(29,855)
Balance at December 31, 2019	—	—	23,968,178	89,345	54,600,000	750	—	—	—	—	2,295	(148,354)	(47)	(56,011)
Issuance of Series D convertible preferred stock for cash, net of $4,317 of issuance costs	140,626,711	68,183	—	—	—	—	—	—	—	—	—	—	—	—
Issuance of Series D convertible preferred stock in connection with settlement of convertible promissory notes	59,164,808	30,594	—	—	—	—	—	—	—	—	—	—	—	—
Assumption of profits interest liability by affiliate	—	—	—	—	—	—	—	—	—	—	991	—	—	991
Change in profits interest liability of affiliate	—	—	—	—	—	—	—	—	—	—	749	—	—	749
Noncontrolling interest—distribution of net assets to affiliate and related deconsolidation	—	—	—	—	—	—	—	—	—	—	(66)	—	47	(19)
LLC Conversion	—	—	(23,968,178)	(89,345)	(54,600,000)	(750)	6,220,050	1	—		(3,196)	93,290	—	—
Conversion of Series D convertible preferred stock into common stock	(199,791,519)	(98,777)	—	—	—	—	13,876,510	1	1,492,059	—	98,776	—	—	98,777
Initial public offering, net of $19,032 of issuance costs	—	—	—	—	—	—	12,075,000	1	—	—	198,317	—	—	198,318
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	3,022	—	—	3,022
Net loss	—	—	—	—	—	—	—	—	—	—	—	(35,853)	—	(35,853)
Balance at December 31, 2020	—	—	—	—	—	—	32,171,560	3	1,492,059	—	300,888	(90,917)	—	209,974
Issuance of common stock, net of $4,007 of issuance costs	—	—	—	—	—	—	2,678,600	1	—	—	70,993	—	—	70,994
Issuance of common stock under equity incentive plans	—	—	—	—	—	—	930,144	—	—	—	—	—	—	0
Issuance of common stock upon exercise of options, net	—	—	—	—	—	—	7,747	—	—	—	140	—	—	140
Issuance of common stock for Employee Stock Purchase Plan	—	—	—	—	—	—	11,182	—	—	—	289	—	—	289
Taxes related to net share settlement of equity awards	—	—	—	—	—	—	—	—	—	—	(291)	—	—	(291)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	25,117	—	—	25,117
Net loss	—	—	—	—	—	—	—	—	—	—	—	(95,402)	—	(95,402)
Balance at December 31, 2021	—	$ —	—	$ —	—	$ —	35,799,233	$ 4	1,492,059	$ —	$ 397,136	$ (186,319)	$ —	$ 210,821

See accompanying notes.

BioAtla, Inc.
Consolidated statements of cash flows
(in thousands)

	Years ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities			
Net loss	$ (95,402)	$ (35,853)	$ (29,855)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,330	1,008	860
Loss on disposal of property and equipment	4	—	3
Change in fair value of derivative liability	—	1,581	63
Change in fair value of profits interest liability	—	(6,852)	(6,403)
Loss/(gain) on extinguishment of debt	(690)	2,883	—
Stock-based compensation	25,117	3,022	—
Non-cash interest	—	525	355
Accrued interest	3	864	1,276
Deferred rent	—	(150)	230
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(237)	(1,273)	939
Accounts payable and accrued expenses	7,992	(1,660)	3,218
Accounts payable and accrued expenses—related parties	—	—	(88)
Deferred revenue	—	(429)	19,757
Right-of-use assets and lease liabilities, net	(331)	—	—
Net cash used in operating activities	(62,214)	(36,334)	(9,645)
Cash flows from investing activities			
Purchases of property and equipment	(924)	(590)	(1,509)
Net cash used in investing activities	(924)	(590)	(1,509)
Cash flows from financing activities			
Noncontrolling interest	—	(19)	(5)
Proceeds from issuance of convertible debt	—	2,750	4,000
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	68,183	—
Proceeds from issuance of PPP loan	—	682	—
Proceeds from initial public offering, net of issuance costs	—	200,229	—
Payment of initial public offering costs	(1,911)	—	—
Proceeds from issuance of common stock	70,994	—	—
Proceeds from exercise of stock options	140	—	—
Proceeds from issuance of common stock under Employee Stock Purchase Plan	289	—	—
Net cash provided by financing activities	69,512	271,825	3,995
Net increase (decrease) in cash and cash equivalents	6,374	234,901	(7,159)
Cash and cash equivalents, beginning of period	238,605	3,704	10,863
Cash and cash equivalents, end of period	$ 244,979	$ 238,605	$ 3,704
Supplemental disclosure of non-cash investing and financing activities			
Property and equipment additions included in accounts payable and accrued expenses	$ 1	$ 17	$ 172
Fair value of warrants issued by affiliates in connection with modification of convertible promissory notes	$ —	$ —	$ 764
Assumption of profits interest liability by affiliates	$ —	$ 991	$ 997
Equity issuance costs included in accounts payable and accrued expenses	$ —	$ 1,911	$ —
Carrying value of convertible promissory notes settled in connection with Corporate Reorganization	$ —	$ 27,711	$ —
Fair value of consideration issued in connection with settlement of convertible promissory notes	$ —	$ 30,594	$ —
Tax related to net settlement of equity awards included in accounts payable and accrued expenses	$ 291	$ —	$ —

See accompanying notes.

BioAtla, Inc.
Notes to consolidated financial statements

1. Organization and summary of significant accounting policies

Organization

BioAtla, LLC was formed in Delaware in March 2007 and, after undergoing two separate reorganizations that are further discussed below, was converted to a Delaware corporation in July 2020 and was renamed BioAtla, Inc. (BioAtla, Inc. together with the Pre-Division Predecessor and the Post-Division Successor as defined below, 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.

LLC Division

In March 2019, BioAtla, LLC (the "Pre-Division Predecessor") was divided into three separate and distinct Delaware limited liability companies (the "Division") as follows: 1) BioAtla, LLC renamed to BioAtla Holdings, LLC ("BioAtla Holdings"), 2) a new legal entity named Inversagen, LLC ("Inversagen"), and 3) a new legal entity named BioAtla, LLC (the "Post-Division Successor" and together with BioAtla Holdings and Inversagen, the "Post-Division LLCs"). Upon the Division, each Post-Division LLC had substantially the same form of operating agreement and capital structure as the Pre-Division Predecessor, with the following exceptions: i) 1,750,000 Class B units issued by the Post-Division Successor but not by BioAtla Holdings or Inversagen, ii) the outstanding warrants of the Pre-Division Predecessor at the Division date were transferred to the Post-Division Successor (see Note 7), and iii) the Class C units of the Post-Division Successor had liquidation preferences and a preferred return not included in the operating agreements of BioAtla Holdings and Inversagen.

In connection with the Division, the Pre-Division Predecessor's holdings of EXUMA Biotech Corp. ("EXUMA", formerly F1 Oncology, Inc.) common and preferred stock (see Note 12) remained in BioAtla Holdings and certain rights related to the application of CAB technology in senescent cell therapy were transferred to the Post-Division Successor and simultaneously licensed to Inversagen (see Note 10). The remaining assets and liabilities (including ownership of Himalaya Therapeutics SEZC, or "HTKY", and its wholly-owned subsidiary, Himalaya Therapeutics HK Limited as described below in "Principles of consolidation and deconsolidation"), and substantially all of the operations of the Pre-Division Predecessor, including all existing employees, were transferred to the Post-Division Successor. Each of the Pre-Division Predecessor's members at the time of the Division continued as a member in the Post-Division Successor, BioAtla Holdings and Inversagen, and each entity has Dr. Jay Short and his spouse, Carolyn Anderson Short, as its LLC managers. There are no shared services agreements between the Company and BioAtla Holdings or Inversagen. The Company has determined that Inversagen is a variable interest entity ("VIE"), the Company is not the primary beneficiary of Inversagen, and that the Post-Division LLCs are under the common control of Jay and Carolyn Short. The Company does not consolidate either BioAtla Holdings or Inversagen (see Note 10). In addition, the Company has no direct equity investment in either BioAtla Holdings or Inversagen that require either equity method or cost method accounting.

The assets, liabilities, and employees transferred to the Post-Division Successor in the Division met the definition of a business and the transfer qualifies as a change in reporting entity under Accounting Standards Codification ("ASC") 250-10-45-21. As such, the historical financial statements of the Pre-Division Predecessor are deemed to be those of the Post-Division Successor, even for periods prior to its formation. As a transfer of a business to an entity under common control, the assets and liabilities of the Pre-Division Predecessor were transferred to the Post-Division Successor at historical carrying values. At the Division date, the Pre-Division Predecessor's investment in EXUMA and the assets licensed to Inversagen had a zero carrying value and neither EXUMA nor Inversagen had material operations. As such, the Pre-Division historical financial statements presented herein are the historical financial statements of the Pre-Division Predecessor without adjustment.

In connection with the Division, certain modifications were made to then outstanding debt agreements and units, including: i) the participation threshold of each Class B unit in each Post-Division LLC was adjusted for the impact of the Division (see Note 8), ii) the amendment of the Pfizer Note and 2018 Notes (as defined and described in Note 4), and iii) the issuance, to both Pfizer and the holders of the 2018 Notes, of conditional warrants by BioAtla Holdings and Inversagen which become exercisable upon the conversion of the Pfizer Note and 2018 Notes into capital stock of the Post-Division Successor (see Note 4).

The Post-Division Successor converted to a Delaware corporation in July 2020 as part of the Corporate Reorganization defined and described below, and was renamed BioAtla, Inc. BioAtla, Inc. is the final successor to the Pre-Division Predecessor and the Post-Division Successor, and collectively these entities are referred to as "the Company." The historical financial statements of the Company prior to the Corporate Reorganization are those of the Pre-Division Predecessor and the Post-Division Successor without adjustment.

Corporate Reorganization and Series D Financing

In July 2020, BioAtla, LLC (the Post-Division Successor) completed a series of transactions (the "Corporate Reorganization") in connection with the conversion from a limited liability company into a Delaware corporation, the spin-off of Himalaya Therapeutics SEZC, and the completion of a Series D convertible preferred stock financing. The Corporate Reorganization involved the formation of Himalaya Parent LLC as a wholly owned subsidiary of BioAtla, LLC and the formation of BioAtla MergerSub LLC, as a wholly owned subsidiary of Himalaya Parent LLC. Under the Agreement and Plan of Merger (the "Merger Agreement"), BioAtla, LLC was merged into and with BioAtla MergerSub LLC, with BioAtla, LLC surviving, and the members of BioAtla, LLC immediately prior to the effective time of the Merger Agreement received membership interests, on a one-for-one basis, of Himalaya Parent LLC as consideration, and the then-outstanding warrants to purchase equity of BioAtla, LLC were converted into warrants to purchase common shares of common stock of BioAtla, Inc. (see Note 7). The Himalaya Parent

LLC operating agreement provided identical equity rights for the then outstanding units of BioAtla, LLC. In addition: (i) the membership interests of BioAtla, LLC held by Himalaya Parent LLC were exchanged for 6,220,050 shares of BioAtla, Inc. common stock, (ii) BioAtla, Inc. issued an aggregate of 59,164,808 shares of Series D convertible preferred stock to Himalaya Parent LLC and Himalaya Parent LLC issued an aggregate of 59,164,808 Class D units to the holders of convertible notes of BioAtla, LLC in connection with the conversion of their convertible notes into Class D units of Himalaya Parent LLC (see Note 4), (iii) BioAtla, LLC distributed to Himalaya Parent LLC its equity interests in Himalaya Therapeutics SEZC, a then majority-owned subsidiary which is engaged in the development of a set of antibodies in the field of oncology primarily in Greater China, (iv) Himalaya Parent LLC assumed the profits interest liability of BioAtla, LLC (see Note 8) and (v) BioAtla, LLC converted into a Delaware corporation pursuant to a statutory conversion and changed its name to BioAtla, Inc. Following the Corporate Reorganization, Himalaya Parent LLC owned 59,164,808 shares of BioAtla, Inc. Series D convertible preferred stock and 6,220,050 shares of BioAtla, Inc. common stock, all of which were subsequently distributed ("the Distribution") to the members of Himalaya Parent, LLC. As a result of the sale of 140,626,711 shares of Series D convertible preferred stock to new investors in July 2020 (see Note 7), BioAtla, Inc. was not controlled by Himalaya Parent LLC and BioAtla, Inc. does not control Himalaya Parent LLC subsequent to the distribution discussed in item (iii) above (see further discussion in “Principles of consolidation and deconsolidation” below). All pre-Corporate Reorganization operations, employees, property, assets and obligations of BioAtla, LLC (exclusive of the profits interest liability and Himalaya Therapeutics SEZC now held by Himalaya Parent LLC) are held by BioAtla, Inc. Shares of Series D convertible preferred stock were subsequently converted into common stock as part of the Company’s initial public offering (“IPO”) in December 2020.

Reverse Stock Split

On December 2, 2020, the Company effected a 1-for-13 reverse stock split of its common stock. The par value and the authorized shares of the common stock were not adjusted as a result of the reverse stock split. The reverse stock split resulted in an adjustment to the convertible preferred stock conversion price to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split. No adjustments have been made to any period for the units outstanding prior to the LLC Conversion.

Principles of Consolidation and Deconsolidation

Prior to the Corporate Reorganization in July 2020, the consolidated financial statements included the accounts of BioAtla, LLC and those of its majority owned subsidiary Himalaya Therapeutics SEZC that had no material operations. Himalaya Therapeutics SEZC also had a wholly owned subsidiary, Himalaya Therapeutics HK Limited that had no material operations. All intercompany balances were eliminated in consolidation. In connection with the Corporate Reorganization, Himalaya Therapeutics SEZC and Himalaya Therapeutics HK Limited were deconsolidated without material impact to the consolidated financial statements. Subsequent to the Corporate Reorganization and subsequent to the Distribution as defined and described above, Himalaya Parent LLC does not control, is not under common control with, and is not consolidated by BioAtla, Inc. and BioAtla, Inc. is a single legal entity with no consolidated variable interest entities ("VIEs") or subsidiaries (see Note 10).

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, 2021, the Company had an accumulated deficit of $186.3 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.

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 for 12 months after the date the consolidated financial statements for the year ended December 31, 2021 are issued.

Variable Interest Entities

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 variable interest entity (“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 Notes 10 and 12).

Use of Estimates

The Company's consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of the Company's consolidated 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 consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to revenue recognition, 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 three months or less when purchased to be cash equivalents.

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. 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.

For the years ended December 31, 2021, 2020, and 2019, BeiGene, as defined and described in Note 9, represented 0%, 100% and 91%, respectively, of total revenues.

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, 2021, 2020, and 2019.

Leases

The Company adopted the Accounting Standard Update ("ASU") 2016-02, Leases, and additional ASUs issued to clarify and update the guidance in ASU 2016-02 (collectively, "ASC 842"), as of January 1, 2021. See the section Recently Adopted Accounting Pronouncements below for more information.

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. The Company elected to use the transition relief package of practical expedients but did not elect to use the hindsight practical expedient in determining a lease term and impairment of ROU assets at the adoption date. For short-term leases, defined as leases with a term of twelve months or less, the Company elected the practical expedient to not recognize an associated lease liability and ROU asset. Lease payments for short-term leases 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 consolidated balance sheets. The Company does not have any finance leases.

Lease Accounting Prior to the Adoption of ASC 842

For operating leases, the Company recorded rent expense using the straight-line method over the lease term, which includes the period of time from when the Company takes possession of the leased space until leasehold improvements are completed and the space is occupied. The difference between rent expense and amounts paid under the lease agreement is deferred in the accompanying consolidated balance sheets. Tenant improvement allowances and other lease incentives are recorded as liabilities and are amortized on the straight-line basis over the lease term as reductions to rent expense.

Beneficial Conversion Features

A beneficial conversion feature is a non-detachable conversion feature that is "in the money" at the commitment date, which requires recognition of interest expense for underlying debt instruments and a deemed dividend for underlying equity instruments. A conversion option is "in the money" if the effective conversion price is lower than the commitment date fair value of the share into which it is convertible.

Accounting for Derivatives

The Company evaluates its convertible instruments and other contracts to determine if those contracts or embedded components of those contracts are required to be recognized under Accounting Standards Codification ("ASC") Topic 815, *Derivatives and Hedging*. The result of this accounting treatment is that the derivative is carried at fair value as an asset or liability with changes in fair value recognized in earnings as they occur. Although separately measured at fair value, the fair value of bifurcated embedded derivatives is presented with the host contract in the consolidated balance sheets. Changes in the fair value of derivatives are recorded in the accompanying consolidated statements of operations and comprehensive loss as a component of other income (expense).

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 consolidated 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, 2021, the Company has accrued $6.2 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 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. Historically, revisions have not resulted in material changes to research and development expense; however, a modification in the protocol of a clinical trial or cancellation of a trial could result in a 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.

Equity-Based Compensation Related to Profits Interest Plan

Prior to the Corporate Reorganization in July 2020, the Company had a profits interest plan that was a liability award plan in accordance with ASC Topic 718, *Compensation – Stock Compensation (Topic 718)*. The Company measured the fair value of each award on the grant date and recognized such fair value over the requisite service period (usually the vesting period) on a straight-line basis. The fair value of the award was remeasured at each reporting date until the award was settled, with a true-up of compensation cost for changes in fair value prorated for the portion of the requisite service period rendered. Once vested, any subsequent change in fair value was recognized immediately. The fair value of any awards that expired or were forfeited or canceled for no value was adjusted to zero, as they occurred, such that any previously recorded compensation cost would be fully reversed. Subsequent to the Corporate Reorganization and amendment of the profits interest plan by Himalaya Parent in October 2020, the Company no longer reflects compensation cost and a corresponding capital contribution associated with the ongoing mark-to-market of the Class B profits interests held by Himalaya Parent LLC.

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 consolidated 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 Unit/Share

Prior to the Corporate Reorganization, the Company applied the two-class method for calculating and presenting net loss per unit. In applying the two-class method, earnings are hypothetically allocated between the common, preferred, and other participating securities based on their respective rights to receive non-forfeitable distributions, whether or not declared. The Company considered its Class A units to be its “common units” since Class A units were the most subordinate class of equity with respect to preference in liquidation. In addition, the Class C units were entitled to a preferred return equal to 10% per annum, simple interest, on the Class C issuance price. The Company’s Class B units were excluded from the net loss per unit calculations based on the presumption that the units would be settled in cash pursuant to the terms of the Company’s operating agreement. Basic net loss per Class A unit was calculated by dividing net loss allocable to Class A unit holders (after adjustment for Class C preferred return and allocation of net losses to Class C units) by the weighted-average number of Class A units outstanding during the period. The Company calculated diluted net loss per unit using the more dilutive of 1) the treasury stock method, if-converted method, or contingently issuable share method, as applicable, or 2) the two-class method. For the year ended December 31, 2019, the basic and diluted net loss per unit were the same as the inclusion of outstanding warrants, convertible debt or Class C preferred units would be antidilutive.

Subsequent to the Corporate Reorganization, basic net loss per 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 common stock warrants, RSUs, and common stock options outstanding under the Company’s stock option plan.

For the year ended December 31, 2020, the Company determined that the attribution of pre-Corporate Reorganization net losses based on the post-Corporate Reorganization capital structure would not meaningfully represent the economic rights of the unit holders. As a result, the Company presents net loss per share information only for the period subsequent to the Corporate Reorganization. The basic and diluted net loss per share for the year ended December 31, 2020 represents only the period from July 10, 2020 to December 31, 2020, the period where the Company had outstanding common stock.

The following table presents the calculation of basic and diluted net loss per share for the period following the Corporate Reorganization (in thousands, except share and per share data):

	July 10, 2020 through December 31, 2020
Numerator:	
Net loss	$ (26,877)
Denominator:	
Weighted-average shares of common stock outstanding, basic and diluted	8,428,153
Net loss per common share, basic and diluted	$ (3.19)

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

	December 31, 2021	December 31, 2020
Common stock warrants	151,088	717,674
Common stock options	1,086,902	615,106
Restricted stock units	975,046	1,920,037
Total	2,213,036	3,252,817

Recent Accounting Pronouncements

Under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, emerging growth companies ("EGC") can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company elected to retain the ability to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that the Company (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. The Company lost its emerging growth company status on December 31, 2021 because the Company became a large accelerated filer due to the fact that the Company's public float exceeded $700 million as of the June 30, 2021 measurement date.

The Company adopted the following accounting standards during the year ended December 31, 2021:

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, Leases. The new standard establishes a right-of-use model and requires a lessee to recognize on the balance sheet a right-of-use asset and corresponding lease liability for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. Effective January 1, 2021, the Company adopted this new standard prospectively using a modified retrospective transition approach. The Company elected the package of practical expedients permitted under the transition guidance of the new standard, which allowed the Company to carry forward its historical assessment on whether a contract is or contains a lease, lease classification, and initial direct costs. Upon adoption on January 1, 2021, the Company recognized operating lease ROU assets of $4.1 million, and current and non-current operating lease liabilities of $1.1 million and $5.4 million, respectively. The difference between the asset and liabilities is primarily attributable to adjustments to the right-of-use asset at transition related to lease incentives and deferred rent. The adoption of ASC 842 did not have a material impact to Company's consolidated statements of operations and cash flows from operations.

In December 2019, the FASB issued ASU No. 2019-12 Income Taxes (Topic 740) Simplifying the Accounting for Income Taxes. The Board issued this Update as part of its Simplification Initiative to improve areas of GAAP and reduce cost and complexity while maintaining usefulness. The main provisions remove certain exceptions including the exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. In addition, the amendments simplify income tax accounting in the areas such as income-based franchise taxes, eliminating the requirements to allocate consolidated current and deferred tax expense in certain instances, and a requirement that an entity reflects the effect of enacted changes in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. For public companies, the standard is effective for fiscal years beginning after December 15, 2020 and interim periods therein. The Company adopted ASU 2019-12 on the effective date of January 1, 2021. The amendments were applied on a prospective basis and the adoption did not have a significant impact on the Company's financial results.

2. Balance sheet details

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

	December 31,	
	2021	2020
Prepaid research and development	$ 1,811	$ 2,004
Other prepaid expenses and current assets	502	72
Total	$ 2,313	$ 2,076

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

		December 31,	
	Useful life (years)	2021	2020
Furniture, fixtures and office equipment	3 - 7	$ 2,123	$ 1,719
Laboratory equipment	5	2,123	1,790
Leasehold improvements	2 - 3	3,687	3,663
		7,933	7,172
Less accumulated depreciation and amortization		(4,257)	(3,070)
Total		$ 3,676	$ 4,102

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

	December 31,	
	2021	2020
Accounts payable	$ 1,179	$ 2,456
Accrued compensation	2,671	2,804
Accrued research and development	13,501	4,852
Accrued equity issuance costs	—	1,143
Other accrued expenses	1,073	813
Total	$ 18,424	$ 12,068

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, 2021 and December 31, 2020, 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.

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.

The 2018 Notes (as amended in 2020), the 2019 Notes and the 2020 Notes (each as defined and described in Note 4) contained a redemption feature which was determined to be an embedded derivative requiring bifurcation and separate accounting. The fair value of the derivative was determined based on an income approach that identified the cash flows using a "with-and-without" valuation methodology. The

inputs used to determine the estimated fair value of the derivative instrument were based primarily on the probability of an underlying event triggering the embedded derivative occurring and the timing of such event.

The following table provides a reconciliation of the embedded derivative liability measured at fair value using Level 3 unobservable inputs (in thousands):

	Embedded derivative liability
Balance at December 31, 2019	$ 1,856
Initial fair value of embedded derivatives issued	3,415
Change in fair value	1,581
Settlement	(6,852)
Balance at December 31, 2020	$ —

4. Convertible and other debt

Pfizer convertible promissory note

In December 2015, the Company issued a $10.0 million unsecured convertible promissory note ("Pfizer Note") to certain affiliates of Pfizer, Inc. ("Pfizer"). The Pfizer Note accrued interest at 8.0% per annum with a maturity date in December 2020. Prior to amendment in March 2019 as described below, the Pfizer Note, including accrued interest, was convertible at the election of the holder into Class C preferred units at a price of $3.394142 per unit and was automatically convertible into i) common shares upon the completion of an IPO based on the price per share paid by investors in the IPO or ii) qualified financing shares upon the completion of a qualified financing based on the price per share paid by investors in the qualified financing. The Company assessed the terms of the Pfizer Note and concluded that it was not share-settled debt, did not contain any embedded derivative features requiring bifurcation and did not contain a beneficial conversion feature. As a result, the Pfizer Note was carried at cost since the Company did not incur a material amount of issuance costs in connection with the debt.

The Pfizer Note was amended in March 2019 in connection with the Division to provide the lender additional accrued interest upon conversion. The amended conversion amount of the Pfizer Note was equal to the greater of a) the then outstanding principal plus accrued interest, or b) principal plus accrued interest through December 7, 2020. In connection with the March 2019 amendment, Pfizer received conditional warrants in BioAtla Holdings and Inversagen which allowed Pfizer to acquire an equity interest in each of BioAtla Holdings and Inversagen upon conversion of the Pfizer Note of the Post-Division Successor. The amendment of the Pfizer Note was accounted for as a modification, which required prospective consideration of the revised terms. The Company recognized the initial fair value of the warrants of $0.5 million as a fee paid by the Company to the lenders, which was recorded as debt discount on the modified debt and as a capital contribution, as the warrants were written on two entities under common control that were not consolidated with the Company. The debt discount was amortized to interest expense using the effective interest method over the term of the Pfizer Note. The fair value of the conditional warrants was determined using the Option Pricing Method based on the underlying value of the assets allocated to BioAtla Holdings and Inversagen. The Company incurred interest expense in connection with the Pfizer Note of $0.6 million and $1.0 million for the years ended December 31, 2020 and 2019. As further described below, the Pfizer Note was amended and settled in connection with the Corporate Reorganization in July 2020.

2018 convertible promissory notes

In August 2018, the Company issued unsecured convertible promissory notes for an aggregate of $5.0 million (the "2018 Notes"). The 2018 Notes accrued interest at 8.0% per annum with a maturity date in July 2023. Prior to amendment in March 2019, as described below, the then outstanding principal plus accrued interest under the 2018 Notes was convertible at the election of the holder into Class C preferred units at a price of $3.394142 per unit and was automatically convertible into i) common shares upon the completion of an IPO based on the price per share paid by investors in the IPO or ii) qualified financing shares upon the completion of a qualified financing based on the price per share paid by investors in the qualified financing. The Company assessed the terms of the 2018 Notes and concluded that they were not share-settled debt, did not contain any embedded derivative features requiring bifurcation and did not contain a beneficial conversion feature. As a result, the 2018 Notes were carried at cost since the Company did not incur a material amount of issuance costs in connection with the issuance of the promissory notes.

The 2018 Notes were amended in March 2019 in connection with the Division to provide the lenders additional accrued interest upon conversion. The amended conversion amount of the 2018 Notes was equal to the greater of a) the then outstanding principal plus accrued interest, or b) principal plus accrued interest through December 7, 2020. In connection with the March 2019 amendment, the lenders received conditional warrants in BioAtla Holdings and Inversagen which allowed them to acquire an equity interest in each of BioAtla Holdings and Inversagen upon conversion of the 2018 Notes of the Post-Division Successor. The amendment of the 2018 Notes was accounted for as a modification, which required prospective consideration of the revised terms. The Company recognized the initial fair value of the warrants of $0.2 million as a fee paid by the Company to the lenders, which was recorded as debt discount on the modified debt and as a capital contribution, as the warrants were written on two entities under common control that were not consolidated with the Company. The debt discount was amortized to interest expense using the effective interest method over the term of the 2018 Notes. The fair value of the conditional warrants was determined using the Option Pricing Method based on the underlying value of the assets allocated to BioAtla Holdings. The underlying value of the assets allocated to Inversagen was immaterial.

The 2018 Notes were amended in April 2020 to add a discount to the conversion prices such that they were convertible (i) automatically into preferred stock upon a qualified equity financing, with a conversion price of 80% of the lowest purchase price per share of preferred stock paid by investors in such qualified equity financing, (ii) automatically convert into common stock upon an initial public offering, with a conversion price of 80% of the price per share of common stock paid by investors in such initial public offering, and (iii) upon the election of each note holder, into Class C preferred units, with a conversion price per share of $2.7153136. The Company concluded that the amendment was an extinguishment and the fair value of the amended 2018 Notes was equal to the then outstanding principal and accrued interest of the 2018 Notes. As a result, the Company recognized a loss on extinguishment for the $0.2 million of unamortized discounts at the extinguishment date.

In addition, the Company assessed the terms and concluded the amended 2018 Notes: (i) were not share-settled debt, (ii) contained a redemption feature that was determined to be an embedded derivative requiring bifurcation and (iii) did not contain a beneficial conversion feature. The $2.2 million issuance date fair value of the embedded derivative liability was recorded as a debt discount and amortized to interest expense using the effective interest method over the remaining term of the 2018 Notes.

The Company incurred interest expense, including coupon interest and amortization of debt discounts, in connection with the 2018 Notes of $0.4 million and $0.4 million for the years ended December 31, 2020 and 2019, respectively. As further described below, the 2018 Notes were amended and settled in connection with the Corporate Reorganization in July 2020.

2019 convertible promissory notes

Between August and December 2019, the Company issued unsecured convertible promissory notes payable to various entities in an aggregate principal amount of $4.0 million (the “2019 Notes”), of which $1.5 million was to related parties. The 2019 Notes accrued interest at 8.0% per annum with maturity dates of five years after issuance. The outstanding principal amount and any accrued and unpaid interest on the 2019 Notes was due and payable on the earlier to occur of (i) the maturity date, (ii) an event of default, or (iii) immediately prior to an acquisition event. The 2019 Notes were convertible (i) automatically into preferred stock upon a qualified equity financing, with a conversion price of 80% of the lowest purchase price per share of preferred stock paid by investors in such qualified equity financing, (ii) automatically into common stock upon an initial public offering, with a conversion price of 80% of the price per share of common stock paid by investors in such initial public offering, and (iii) upon the election of each note holder, into Class C preferred units, with a conversion price per share of $2.7153136. The number of shares or units issuable upon conversion is determined by dividing the conversion amount by the conversion price, with the conversion amount equal to the greater of a) the then outstanding principal plus accrued interest, or b) principal plus accrued interest through December 7, 2020.

The Company assessed the terms and concluded the 2019 Notes: (i) were not share-settled debt, (ii) contained a redemption feature that was determined to be an embedded derivative requiring bifurcation and (iii) certain of the notes contained a beneficial conversion feature because the fair value of the securities into which the 2019 Notes were convertible at the time of issuance, the Class C preferred units, was greater than the effective conversion price of the 2019 Notes. The $0.5 million beneficial conversion feature was recorded as additional paid-in capital and a debt discount and the $1.8 million issuance date fair value of the embedded derivative liability was recorded as a debt discount, both of which discounts were amortized to interest expense using the effective interest method over the term of the 2019 Notes.

In April and May of 2020 certain of the 2019 Notes, representing $2.5 million of the then outstanding principal balance, were amended such that the conversion shares or units issuable upon conversion is the greater of: (i) the then outstanding principal plus accrued interest divided by $0.86866 or (ii) the amount determined by dividing the conversion amount by the conversion price, with the conversion amount equal to the greater of a) the then outstanding principal plus accrued interest, or b) principal plus accrued interest through December 7, 2020. The amendment of the 2019 Notes was accounted for as a modification, which required prospective consideration of the revised terms.

For the year ended December 31, 2020 and 2019, the Company recognized interest expense, including coupon interest and amortization of debt discounts, in connection with the 2019 Notes of $0.3 million and $0.1 million, respectively. As further described below, the 2019 Notes were amended and settled in connection with the Corporate Reorganization in July 2020.

2020 convertible promissory notes

During March, April and May of 2020 the Company issued unsecured convertible promissory notes (the “2020 Notes”) payable to various entities in an aggregate principal amount of $2.8 million, of which $0.5 million was to related parties. The 2020 Notes accrued interest at 8.0% per annum with maturity dates of five years after issuance. The Company assessed the terms and concluded the 2020 Notes: (i) were not share-settled debt,(ii) contained a redemption feature that was determined to be an embedded derivative requiring bifurcation and (iii) did not contain a beneficial conversion feature. The $1.2 million issuance date fair value of the embedded derivative liability was recorded as a debt discount which was amortized to interest expense using the effective interest method over the term of the 2020 Notes. In May of 2020 certain of the 2020 Notes, representing $0.1 million of the then outstanding principal balance, were amended such that the conversion shares or units issuable upon conversion is the greater of: (i) the then outstanding principal plus accrued interest divided by $0.86866 or (ii) the amount determined by dividing the conversion amount by the conversion price, with the conversion amount equal to the greater of a) the then outstanding principal plus accrued interest, or b) principal plus accrued interest through December 7, 2020. The amendment of the 2020 Notes was accounted for as a modification, which required prospective consideration of the revised terms.

For the year ended December 31, 2020, the Company recognized interest expense, including coupon interest and amortization of debt discounts, in connection with the 2020 Notes of $0.1 million. As further described below, the 2020 Notes were amended and settled in connection with the Corporate Reorganization in July 2020.

Amendment and settlement of convertible notes

As a condition of the closing of the Series D financing in July 2020, the Pfizer Note, 2018 Notes, 2019 Notes and 2020 Notes (and together, the "Convertible Notes") were amended to settle the Convertible Notes into 59,164,808 Class D units of Himalaya Parent LLC. As of the settlement date, the aggregate outstanding principal and accrued interest of the Convertible Notes was $21.8 million and $4.7 million, respectively. The Pfizer Note converted into Class D units at a conversion price of $0.51554931 and the 2018 Notes and 2019 Notes converted into Class D units at a conversion price of $0.412439448, which is 80% of the price paid by investors in the Series D financing. As of the July 10, 2020 settlement date, the Convertible Notes had a carrying value of $27.9 million, including related accrued interest, embedded derivatives and unamortized debt discounts. The fair value of the Class D units of Himalaya Parent LLC issued to the noteholders in exchange for the Convertible Notes was $30.6 million, resulting in a loss on extinguishment of convertible debt of $2.7 million. The fair value per unit of the Class D units of Himalaya Parent LLC was based on the fair value per share paid by investors in the Company's Series D financing.

Other Debt

In April 2020, the Company borrowed $0.7 million under the Paycheck Protection Program ("PPP") under the CARES Act. The loan was subsequently forgiven in July 2021. The $0.7 million balance of the forgiven loan was recognized as other income on the Company's Statement of Operations and Comprehensive Loss for the twelve months ended December 31, 2021.

5. 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. However, it is not reasonably certain the Company will exercise the option to renew when the lease term ends and thus, the incremental term was excluded from the calculation of the lease liability. Additionally, the lease includes certain rent abatement, rent escalations, tenant improvement allowances and additional charges for common area maintenance and other costs.

Supplemental balance sheet information related to lease liabilities at December 31, 2021, was as follows (in thousands):

Lease-Related Assets and Liabilities	Financial Statement Line Items	As of December 31, 2021
Right-of-use assets:		
Operating leases	Operating lease right-of-use assets	$ 3,300
Total right-of-use assets		$ 3,300
Lease Liabilities:		
Operating leases	Operating lease liabilities	$ 1,389
	Operating lease liabilities, noncurrent	3,982
Total lease liabilities		$ 5,371

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

	Year Ended December 31, 2021
Operating lease expense	$ 1,043
Variable lease expense	512
Total lease expense, net	$ 1,555

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, 2021.

The weighted average remaining lease term and weighted average discount rate for operating leases as of December 31, 2021 were as follows:

	Year Ended December 31, 2021
Weighted average remaining lease term (in years)	3.5
Weighted average discount rate percentage	3.50 %

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

	Year Ended December 31, 2021
Cash paid for amounts included in the measurement of operating leases	$ 1,374

Maturities of operating lease liabilities as of December 31, 2021 were as follows (in thousands):

Years ending December 31:	Operating lease
2022	$ 1,555
2023	1,636
2024	1,685
2025	845
Thereafter	—
Total future lease payments	5,721
Less imputed interest	(350)
Total operating lease liabilities	$ 5,371

As of December 31, 2020, prior to the Company's adoption of ASC 842, annual minimum payments under noncancelable operating leases were as follows (in thousands):

Years ending December 31:	Operating lease
2021	$ 1,374
2022	1,555
2023	1,636
2024	1,685
Thereafter	845
Total minimum lease payments	$ 7,095

Under ASC 840, during the years ended December 31, 2020 and 2019, net rent expense was $1.7 million and $1.1 million, respectively.

6. 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.

7. Convertible preferred stock and members'/stockholders' equity (deficit)

Convertible preferred stock

The Company had convertible preferred stock outstanding between the date of its Series D financing in July 2020 until the closing of its IPO in December 2020. The Company's convertible preferred stock was classified as temporary equity in the accompanying consolidated balance sheets in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change in control events outside of the Company's control, including liquidation, sale or change of control of the Company. Because these change in control events were not probable, the Company did not adjust the carrying values of the convertible preferred stock to redemption value.

Series D financing

On July 13, 2020, BioAtla, Inc. entered into a Series D Preferred Stock Purchase Agreement, pursuant to which it issued 140,626,711 shares of Series D convertible preferred stock at $0.51554931 per share, for aggregate cash proceeds of $72.5 million. The Company incurred $4.3 million of issuance costs.

Initial public offering and related transactions

In December 2020, the Company completed its IPO selling 12,075,000 shares its common stock at $18.00 per share. Proceeds from the Company's IPO, net of underwriting discounts and commissions and other offering costs, were $198.3 million. In connection with the IPO, all 199,791,519 shares of convertible preferred stock outstanding at the time of the IPO converted into 13,876,510 shares of the Company's common stock and 1,492,059 shares of the Company's Class B common stock.

Private Placement of Common Stock

In September 2021, the Company entered into agreements to sell 2,678,600 shares of its common stock at a price of $28.00 per share through a private investment in public equity financing (or "Private Placement"). Proceeds from the Private Placement, net of underwriting discounts and commissions and other offering costs, were $71.0 million.

In connection with the Private Placement, the Company also issued registration rights to the investors. The Company filed a registration statement on Form S-1 (File No. 333-260440) with the SEC registering for resale the shares of common stock issued in the Private Placement.

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.

Operating agreement

Prior to the Corporate Reorganization, the Company's operating agreement, as amended and restated, provided for classes of units, allocation of profits and losses, distribution preferences, other member rights and management of the LLC. The operating agreement designated Class A units, Class B units and Class C preferred units. The Class B units and Class C preferred units were non-voting, except as required by law. The Class B units were liability awards pursuant to authoritative guidance and, as such, were reported at fair value outside of members' deficit. Members were limited in their liability to their capital contributions.

Common stock warrants

The Company issued the warrants described below in 2016 in connection with certain advisory services. The warrants became exercisable upon our 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 described below 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 our IPO expired unexercised. As of December 31, 2021 the remaining common stock warrants below are exercisable and expire as follows:

Outstanding and exercisable	Exercise price per share	Expiration date
151,088	$ 132.37	March 12, 2022

Noncontrolling interests

In December 2018, the Company issued a noncontrolling interest in HTKY in the form of ordinary shares in connection with the termination of a collaboration and license agreement. In addition to the ordinary shares issued, certain employees and shareholders of the Company purchased 19,000,000 ordinary shares of HTKY for an aggregate purchase price of $19,000, of which 5,000,000 were repurchased for $5,000 in March 2019. As of December 31, 2019, the Company held all of the outstanding HTKY preferred equity, consisting of 97,183,256 Series B convertible preference shares, and 1,000 ordinary shares. The Series B convertible preference shares had a liquation preference equal to the greater of $1.00 per share, plus declared and unpaid dividends, or the if-converted value, and pay non-cumulative dividends in preference to the holders of ordinary shares at an annual rate of 7% of the purchase price per share when, as and if declared by the board. The net income (loss) of HTKY was allocated to the ordinary shareholders on a pro rata basis. However, any net income was initially be allocated to the preference shares until the liquidation preference is met. Thereafter, preference shares would only be allocated dividends declared by the board of directors of HTKY. For the year ended December 31, 2019, substantially all of the $61,000 net loss of HTKY was allocated to the noncontrolling interest. HTKY had no material operations for the year ended December 31, 2020. As discussed in Note 1, HTKY was deconsolidated as part of the July 2020 Corporate Reorganization.

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, 2021 and 2020, the total number of common shares authorized for issuance under the 2020 Plan was 6,226,540 and 4,939,678, 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.

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

	Year ended December 31, 2021	Year ended December 31, 2020
Research and development	$ 4,688	$ 740
General and administrative	20,429	2,282
Total	$ 25,117	$ 3,022

Restricted stock units

In December 2020, the Company granted an aggregate of 1,920,037 restricted stock units ("RSUs") to certain of the Company's employees and service providers, including executive officers and non-employee directors.

The following table summarizes RSU activity under the 2020 Plan for the years ended December 31, 2021 and 2020:

	Number of Shares	Weighted - average grant date fair value
Outstanding at December 31, 2019	—	$ —
Granted	1,920,037	$ 18.00
Vested	—	$ —
Outstanding at December 31, 2020	1,920,037	$ 18.00
Granted	—	$ —
Vested	944,991	$ 18.00
Outstanding at December 31, 2021	975,046	$ 18.00

As of December 31, 2021, total unrecognized stock-based compensation expense for RSUs was $17.5 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.2 years.

Stock options

The following table summarizes stock option activity under the 2020 Plan for the year ended December 31, 2021 and 2020 (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, 2019	—	$ —	—	$ —
Granted	615,106	$ 18.00		
Balance at December 31, 2020	615,106	$ 18.00	9.95	$ 9,848
Granted	479,543	$ 37.86		
Exercised	(7,747)	$ 18.00	—	$ 182,829
Balance at December 31, 2021	1,086,902	$ 26.76	9.22	$ 991,495
Vested and expected to vest at December 31, 2021	1,086,902	$ 26.76	9.22	$ 991,495
Exercisable at December 31, 2021	155,579	$ 18.31	8.97	$ 247,486

As of December 31, 2021, total unrecognized stock-based compensation cost for unvested common stock options was $15.0 million, which is expected to be recognized over a remaining weighted-average period of approximately 3.1 years. The weighted- average grant date fair value of stock options granted during the years ended December 31, 2021 and 2020 was $24.61 per share and $11.66 per share, respectively. The total fair value of options vested during the year ended December 31, 2021 was $1.9 million. No options vested during the years ended December 31, 2020 and 2019. 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:

	Year ended December 31, 2021	Year ended December 31, 2020
Expected volatility	74.7 %	74.5 %
Risk-free interest rate	1.06 %	0.52 %
Expected dividend yield	0.0 %	0.0 %
Expected term	5.98 years	6.09 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, 2021 and 2020, a total of 833,993 and 464,829 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). The ESPP plan was amended in September 2021 to change the offering periods to end on May 15th and November 15th of each year beginning January 1, 2022. In February 2021, employees began to enroll in the ESPP and the Company's first offering period commenced. ESPP purchase transactions occurred on June 30, 2021 and on December 31, 2021. During the year ended December 31, 2021, the Company issued 11,182 shares of common stock under the ESPP. As of December 31, 2021, 822,811 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, 2021 was immaterial.

Common stock reserved for future issuance

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

	December 31, 2021	December 31, 2020
Warrants for the purchase of common stock	151,088	717,674
Common stock options and restricted stock units issued and outstanding	2,061,948	2,535,143
Awards available for future issuance under the 2020 Plan	3,211,854	2,404,535
Awards available for future issuance under the ESPP	822,811	464,829
Total common stock reserved for future issuance	6,247,701	6,122,181

8. Profits interest incentive plan

Prior to the Corporate Reorganization in July 2020, the Company maintained a Profits Interest Incentive Plan (the "Plan") for selected employees, consultants and other service providers. In connection with the Corporate Reorganization, Himalaya Parent LLC assumed the Plan and the $1.0 million fair value of the liability was reclassified to additional paid-in capital. As of December 31, 2019, the Company had reserved a total of 16,665,977 Class B units for issuance under the Plan. The Class B units generally vested over four years, were subject to continued service requirements, and only provide the participants with benefits (in the form of distributions) if the distributions from BioAtla exceed specified threshold values. Generally, upon termination of services, all unvested Class B units were forfeited to the Company and the Company had the right, but not the obligation, to repurchase the vested Class B units within two years at the termination date fair value. The Class B unit repurchase would be settled in cash, at all times at the option of the Company, and the holder did not have the right to put the Class B units to the Company under any condition. Vested Class B units that are neither repurchased by the Company nor forfeited remained subject to the terms of the Company's operating agreement. The Class B units were not subject to sale, assignment, transfer, pledge, or allowed to be otherwise encumbered or disposed of without prior written consent of the Company. No Class B units had been repurchased through the date of the Corporate Reorganization.

Activity under the Plan is summarized as follows:

Outstanding at December 31, 2019	14,478,949
Cancelled	(170,836)
Assumption of Plan by Himalaya Parent LLC on July 10, 2020	(14,308,113)
Outstanding at December 31, 2020	—

Vesting of Class B units under the Plan is summarized as follows:

Unvested at December 31, 2019	6,158,328
Cancelled	(170,836)
Vested	(1,310,807)
Assumption of unvested Class B units by Himalaya Parent LLC on July 10, 2020	(4,676,685)
Unvested at December 31, 2020	—

The Class B units were liability awards pursuant to authoritative guidance, which required the Company to record a liability based on the fair value of the Class B units as of each reporting period. Through the date of the Corporate Reorganization, the fair value of the liability awards was determined based on the Company's estimated enterprise value, which was allocated based on a hybrid model that, in addition to the option pricing model, considering the Company's expected IPO. Under the option pricing method, units were valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each unit class.

In connection with the Division, the distribution thresholds that had to be achieved before the Class B unit holders were entitled to distributions were adjusted, resulting in a $0.9 million reduction to the aggregate profits interest liability between the Predecessor and the Post-Division LLCs at the date of the Division. The thresholds of the Post-Division Successor were changed in order to reflect the impact of the assets assigned to BioAtla Holdings and Inversagen in the Division. For the year ended December 31, 2019, the profits interest liability decreased $7.4 million, including the $0.9 million reduction described above, and $0.8 million recognized as additional paid-in capital related to the fair value of vested Class B units assumed by BioAtla Holdings and Inversagen in connection with the Division. In addition, the Company recognized stock-based compensation expense and additional paid-in capital of $0.2 million related to the fair value of the unvested Class B units assumed by BioAtla Holdings and Inversagen in connection with the Division since these Class B unit holders were employees of the Post-Division Successor, and were not expected to provide services to BioAtla Holdings or Inversagen.

The following table provides a reconciliation of the profits interest liability (in thousands):

Balance at December 31, 2019	8,592
Decrease in fair value of vested liability (Pre-Corporate Reorganization) recognized as decrease to stock-based compensation expense	(7,601)
Fair value of vested liability assumed by Himalaya Parent LLC on July 10, 2020 recognized as additional paid-in capital	(991)
Balance at December 31, 2020	$ —

The allocation of equity-based compensation, including $0.7 million from Himalaya Parent as a capital contribution during 2020, for all Class B units is as follows (in thousands):

	Years ended December 31,	
	2020	2019
Research and development	$ (2,993)	$ (2,997)
General and administrative	(3,859)	(3,406)
Total	$ (6,852)	$ (6,403)

9. 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"), a commercial-stage biopharmaceutical company, for the development, manufacturing and commercialization of the Company's investigational CAB CTLA-4 antibody (BA3071). The Company and BeiGene amended the Global Co-Development and Collaboration agreement in December 2019 and in October 2020 (the "Amended BeiGene Collaboration").

Under the BeiGene Collaboration, the Company would co-develop the CAB-CTLA-4 antibody to reach defined early clinical objectives ("POC Milestone"), whereby the Company would perform the development activities and BeiGene would reimburse the Company for a portion of the costs incurred by the Company. Following the POC Milestone, BeiGene would then lead the parties' joint efforts to develop the product candidate and be responsible for global regulatory filings and commercialization. BeiGene would be responsible for all costs of development, manufacturing and commercialization in China, parts of the Middle East and Asia (excluding Japan), Australia and New Zealand (the "BeiGene Territory"), and the parties would share development and manufacturing costs and commercial profits and losses upon specified terms in the rest of the world that are not part of the BeiGene Territory (the "ROW").

In 2019, BeiGene paid the Company an upfront non-refundable payment of $20.0 million and paid the Company $5.0 million for reimbursement of manufacturing costs. Under the BeiGene Collaboration, the Company was eligible to receive variable consideration for subsequent development and regulatory milestones globally and commercial milestones in the BeiGene Territory and tiered royalties ranging from the mid-single digits to the mid-double digits based on net sales in the BeiGene Territory.

The Company concluded that the BeiGene Collaboration was a contract with a customer and applied relevant guidance from Topic 606 through reaching the POC milestone as the licenses to intellectual property granted to BeiGene and the obligation to perform research and development services are outputs of the Company's ongoing activities. The Company identified material promises in the BeiGene Collaboration through POC Milestone, consisting of the licenses described above and the development services. It was determined that the licenses were not distinct from the development services resulting in a single performance obligation.

In accordance with Topic 606, the Company determined the transaction price of the agreement was limited to the $25.0 million received, and excluded the variable consideration of expense reimbursements, milestone payments and royalties as they were fully constrained. The expense reimbursements were included in the transaction price in the reporting period the Company concluded it was probable that inclusion of such amounts in the transaction price would not result in a significant reversal in revenue recognized. As part of the Company's evaluation of the milestone constraints, the Company determined the achievement of such milestones were contingent upon success of future developments, regulatory approvals and commercial activities which were not within its control and were uncertain. Variable consideration related to royalties would be recognized when the related sales occurred.

Under the terms of the Amended BeiGene Collaboration, BeiGene was generally responsible for developing BA3071 and for global regulatory filings and commercialization. Subject to the terms of the Amended BeiGene Collaboration, BeiGene held an exclusive license with the Company to develop and manufacture the BA3071 candidate globally, and BeiGene was responsible for all costs of development, manufacturing and commercialization globally. The Amended BeiGene Collaboration provided that the Company was eligible to receive tiered royalties on sales worldwide, subsequent development and regulatory milestone payments globally and commercial milestones in the BeiGene

territory.

Under the Amended BeiGene Collaboration, the Company's amended performance obligation would be satisfied at a point in time determined to be when BeiGene received the know-how and master cell bank for BA3071. Until then BeiGene could not benefit from the ability to further develop and manufacture the BA3071 candidate. Under the original collaboration agreement, the Company recognized revenue over time using an input method based on actual costs incurred compared to estimated total costs expected to be incurred to fulfill its performance obligation to perform development services.

On November 18, 2021, the Company entered into Amendment No. 3 to the Amended BeiGene Collaboration ("Amendment No.3"). Under Amendment No. 3, the Amended 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 will assume responsibility for the global development and commercialization of BA3071. As consideration for Amendment No.3, 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 BA3071. As part of Amendment No.3, the Company reclassified its 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.

For the year ended December 31, 2021, the Company did not recognize any revenue related to the collaboration agreement with BeiGene. Collaboration revenue recognized for the years ended December 31, 2020 and 2019 was $0.4 million and $5.2 million, respectively. As of December 31, 2021 and December 31, 2020, the Company had a $19.8 million Liability to Licensor, and $19.8 million of deferred revenue which was classified as current, respectively.

Service Contracts

Prior to developing its own programs, the Company entered into various fixed price research services contracts. In connection with these service contracts, the Company may receive future milestone payments if certain clinical, regulatory and commercialization milestones are achieved. The Company is also eligible to receive royalties based on certain product sales. The Company recognized revenue of $0.3 million for the year ended December 31, 2021, related to the achievement of a clinical milestone on a fixed price service contract.

License and Option Agreement with Pfizer, Inc.

The Company was party to a license and option agreement with Pfizer that was terminated in December 2019. Pfizer paid the Company $1.0 million in December 2015 upon execution of the agreement. The Company had identified a single deliverable at inception of the agreement, which consisted of the company's obligation to nominate targets, perform certain preclinical research, efficacy studies and related reports ("research and development services"). These services were prerequisites to Pfizer's exercise of Pfizer's substantive options, including the option to obtain exclusive licenses to develop and commercialize a certain number of Antibody Drug Conjugates ("ADC") CAB antibodies, under the agreement. As such, the Company recognized revenue for the consideration received over the four-year period over which it delivered its research and development services. In connection with the license and option agreement with Pfizer, the Company recognized collaboration revenue of $0.5 million for the year ended December 31, 2019.

10. Related party transactions

Dr. Jay Short and Carolyn Anderson Short

Dr. Jay Short and Carolyn Anderson Short loaned the Company $1.0 million and $0.5 million, respectively, under the terms of the 2019 Notes and 2020 Notes described in Note 4 above. For the years ended December 31, 2020 and 2019, the Company recognized interest expense (including amortization of debt discounts) of $0.1 million and $32,000, respectively, on outstanding 2019 Notes and 2020 Notes payable to Dr. Jay Short and Carolyn Anderson Short. The 2019 Notes and 2020 Notes payable to Dr. Jay Short and Carolyn Anderson Short were settled in connection with the Corporate Reorganization in July 2020.

On March 18, 2021, the Company and Carolyn Anderson Short, its co-founder and former Chief of Intellectual Property & Strategy, mutually agreed that Ms. Short would depart the Company on May 31, 2021 following an agreed upon transition period. The Transition Agreement provides for the following severance benefits in exchange for a release of claims by Ms. Short: (i) a lump sum payment equal to eighteen (18) months of Ms. Short's current base salary, (ii) a payment at her targeted bonus rate for 2021, pro-rated to the separation date, and (iii) accelerated full vesting of her equity awards including 7,747 stock options and 138,461 restricted stock units. The modification of these equity awards resulted in an incremental fair value of $7.0 million which was recognized on a straight-line basis over the transition service period. For the twelve months ended December 31, 2021, the Company recognized $1.0 million related to the lump sum salary payment and target bonus. The Company also recognized non-cash stock-based compensation charges of $9.4 million related to the modified equity awards for the twelve months ended December 31, 2021. No unrecognized stock-based compensation remained as of December 31, 2021. Ms. Short exercised her 7,747 stock options in 2021, therefore there are no remaining options outstanding related to Ms. Short's transition agreement as of December 31, 2021.

Inversagen, LLC

Inversagen was formed in conjunction with the LLC Division. 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; 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. Inversagen is currently inactive, and 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, 2021 and 2020.

Inversagen is a related party of the Company. Dr. Jay Short and his spouse, Carolyn Anderson Short, 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 under the Amended and Restated EXUMA License defined and described in Note 12 below.

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, 2021 and 2020.

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

Himalaya Therapeutics SEZC

Prior to the Corporate Reorganization, Himalaya Therapeutics SEZC met the definition of a VIE under ASC 810-10, as the entity did not have enough equity to finance its activities without additional subordinated financial support. The Company consolidated Himalaya Therapeutics SEZC as the primary beneficiary, as it had (i) the power to direct activities of a VIE that most significantly impact the VIE's economic performance and (ii) the right to receive benefits from the VIE that could potentially be significant to the VIE, resulting from its control of the board of directors, and voting control of the entity via a voting agreement among its shareholders, and its equity holdings. The Company was not obligated to provide financial support to Himalaya Therapeutics SEZC. Himalaya Therapeutics SEZC's creditors had no recourse in the general credit of the Company. Himalaya Therapeutics SEZC held intellectual property related to certain CAB Antibodies under an Exclusive Rights

Agreement with the Company dated December 20, 2018. As of December 31, 2019, Himalaya Therapeutics SEZC had no material operations, did not have any employees and the carrying value of its assets and liabilities was nominal.

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 us 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.

As part of the Corporate Reorganization, Himalaya Therapeutics SEZC was distributed to Himalaya Parent LLC at the carrying value of its assets and liabilities, which were nominal, and no gain or loss was recorded on the transaction in the Company's financial statements for the year ended December 31, 2020. Himalaya Therapeutics SEZC continues to be a variable interest entity 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, 2020 associated with its variable interest in Himalaya Therapeutics SEZC, and has no exposure to Himalaya Therapeutics SEZC losses. The Company does not have a variable interest in Himalaya Parent LLC.

Himalaya Therapeutics SEZC is a related party whose controlling shareholder is Himalaya Parent LLC. Dr. Jay Short and his spouse, Carolyn Anderson Short, serve as directors of Himalaya Therapeutics SEZC, and Carolyn Anderson Short serves as an officer of such entity.

Himalaya Parent LLC

In connection with the Corporate Reorganization, Himalaya Parent assumed the Company's profits interest plan, including equity awards to employees of the Company. For the years ended December 31, 2021 and 2020, the Company recognized $0 and $0.7 million, respectively, of compensation cost and a related capital adjustment in connection with the assumed profits interest plan. Dr. Jay Short and his spouse, Carolyn Anderson Short, serve as managers of Himalaya Parent LLC.

EXUMA Biotech Corp. and subsidiary

As of December 31, 2019, the Company and EXUMA are no longer related parties since none of the Post-Division LLCs own any common or preferred stock of EXUMA and have no ongoing contractual relationships other than the license agreement described below (see Note 12). The Company was a named party to a lease where a subsidiary of EXUMA was the primary tenant. The EXUMA subsidiary paid the landlord directly for payments due under the lease and was reimbursed by the Company for its share of the payments. For the year ended December 31, 2019, the Company expensed $15,000 for its share of payments due under the lease. In addition, the Company expensed $10,000 related to a November 2019 amendment of the license agreement described in Note 12.

Biotech Investment Group, LLC

Prior to the Corporate Reorganization, Biotech Investment Group, LLC ("BIG"), was a principal owner, related party of the Company and affiliated with BioDuro, LLC ("BioDuro") and Biotech Investment Group II LLC ("BIG II"). Subsequent to the Corporate Reorganization, BIG is no longer a principal owner and, as a result, neither BIG nor its affiliates are related parties of the Company.

BioDuro-Sundia

BioDuro-Sundia is a contract research organization that provides services to the Company. For the year ended December 31, 2019, the Company incurred expenses of $1.9 million in connection with services provided by BioDuro-Sundia. During 2019, an affiliate of BIG sold a majority interest in BioDuro-Sundia to an unaffiliated entity. Effective January 1, 2020, BioDuro-Sundia is no longer considered a related party of the Company.

Biotech Investment Group II LLC

BIG II loaned the Company $0.5 million under the terms of the 2019 Notes described in Note 4 above. For the years ended December 31, 2020 and 2019, the Company recognized interest expense (including amortization of debt discounts) of $42,000 and $20,000, respectively on outstanding 2019 Notes payable to BIG II. The 2019 Notes payable to BIG II were settled in connection with the Corporate Reorganization in July 2020.

Private Placement of Common Stock

As part of the 2021 Private Placement, the Company issued 625,000 shares of common stock for total net proceeds of $17.5 million to certain stockholders considered to be related parties.

11. 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.

12. EXUMA Biotech Corp.

Exclusive License Agreement

Under an Exclusive License Agreement entered into in May 2016, the Company granted EXUMA and its affiliates an exclusive, worldwide, sublicensable license under certain patents and know-how controlled by the Company to develop, manufacture and commercialize Adoptive Cellular Therapy ("ACT") preparations and treatments for 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 the Company's CAB ACT technology, except as used in or incorporated into EXUMA's ACTs for cancer. The license to EXUMA is royalty bearing.

EXUMA granted the Company an exclusive, worldwide, royalty free, fully paid-up, sublicensable license under certain patents and know-how controlled by EXUMA and EXUMA's interest in technology jointly developed under the agreement to develop, manufacture and commercialize non-ACT CAB products for any indication.

EXUMA is obligated to pay the Company during the royalty term, on a product-by-product basis and country-by-country basis, mid-single digit royalties based on annual net sales of certain EXUMA ACT products, subject to certain adjustments. The term during which EXUMA is obligated to pay royalties under the agreement with respect to any particular product in any particular country, will begin on the first commercial sale of such product in such country and will end on the date of expiration of the last-to-expire of certain product-related patent rights in such country. All royalties to be paid under the agreement are subject to certain adjustments. Future royalties will be recognized when earned.

Unless earlier terminated, the agreement continues in effect so long as EXUMA or any of its affiliates, licensees or sublicensees are developing or commercializing any EXUMA products in the ACT field or the Company or any of its affiliates, licensees or sublicensees are developing or commercializing any CAB products for any indication outside the ACT field. The agreement may be terminated only by the mutual written agreement of the parties.

In connection with the Exclusive License Agreement, the Pre-Division Predecessor received common and preferred stock of EXUMA. The preferred stock was accounted for as a cost method investment and the common stock was accounted for as an equity method investment. Both the cost method investment and equity method investment had initial carrying values of zero and neither resulted in adjustments to the consolidated statements of operations for the years ended December 31, 2019. These holdings of EXUMA common and preferred stock were retained by BioAtla Holdings in connection with the LLC Division.

In November 2019, the Company entered into an Amended and Restated Exclusive License Agreement with EXUMA (the "Amended and Restated EXUMA License"). The Amended and Restated EXUMA License curtailed the rights to certain CAB intellectual property previously licensed to EXUMA in exchange for a one-time, non-refundable, non-creditable license fee of $10,000. More specifically, the Amended and Restated EXUMA License limits CAB ACT products to four specified targets, and BioAtla is no longer obligated to provide new targets to EXUMA. The Amended and Restated EXUMA License does not change EXUMA's obligation to pay BioAtla royalties on licensed products. In connection with the Amended and Restated EXUMA License, BioAtla Holdings sold its EXUMA common and preferred holdings back to EXUMA for consideration of $25,000. The Company concluded that the Amended and Restated EXUMA License was priced at fair value and was not influenced by the pricing of the contemporaneous related party stock sale.

EXUMA is a VIE, and the Company has a variable interest in EXUMA due to its right to receive royalties during the royalty term under the Amended and Restated EXUMA License. As of December 31, 2021 and 2020, the Company has determined it is not the primary beneficiary of EXUMA and, as such, the Company does not consolidate EXUMA. The Company has no equity ownership in EXUMA, no representation on the EXUMA board of directors, and the Amended and Restated EXUMA License does not provide the Company with the ability to make decisions regarding the execution of business strategy that most significantly impact the economic performance of EXUMA. The Company has not funded and has no commitment to fund EXUMA's losses, and has no exposure to loss as a result of its Amended and Restated EXUMA License. The Company's financial statements do not include any assets or liabilities related to the Amended and Restated EXUMA License at December 31, 2021 and 2020.

13. Income taxes

Historically, the Company had conducted its U.S. operations through a pass through entity that filed its income tax returns as a partnership for federal and state income tax purposes. As a result, the Company was not subject to U.S. federal or state income taxes as the related tax consequences were reported by its individual members. In July 2020, the Company changed its status from a limited liability company to a corporation, and accordingly, the Company became taxable at the entity level for U.S. federal and state tax purposes.

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):

	Year ended December 31, 2021	Year ended December 31, 2020
Tax computed at the federal statutory rate	$ (20,034)	$ (7,529)
Deferred impact of conversion to C Corporation	(2,131)	(6,708)
Partnership income not subject to tax	—	1,837
Nondeductible executive compensation	4,145	—
Stock-based compensation	(1,021)	—
Research and development and orphan drug credits	(3,091)	(807)
Uncertain tax positions	757	197
Other, net	793	242
Valuation allowance	20,582	12,768
Income tax expense	$ —	$ —

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

	December 31, 2021	December 31, 2020
Deferred tax assets:		
Net operating loss carryforwards	$ 21,935	$ 5,607
Guaranteed payments	—	1,702
Liability to licensor	4,159	—
Deferred revenue	—	4,159
Goodwill	3,449	—
Deferred rent	—	504
Lease liability	1,128	—
Accrued compensation	485	585
Research credit carryforwards	2,945	610
Stock-based compensation	697	438
Other	2	0
Gross deferred tax assets	34,800	13,605
Less valuation allowance	(33,351)	(12,768)
Total deferred tax assets	1,449	837
Deferred tax liabilities:		
Fixed assets	(756)	(837)
Operating lease right-of-use asset	(693)	—
Total deferred tax liabilities	(1,449)	(837)
Net deferred tax assets	$ —	$ —

A valuation allowance of approximately $33.4 million as of December 31, 2021 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 $20.6 million during 2021.

At December 31, 2021, the Company had federal net operating loss carryforwards of approximately $104.5 million. The federal net operating losses can be carried forward indefinitely, subject to an 80% limitation against taxable income.

At December 31, 2021, the Company had federal and California research and development credit carryforwards of approximately $1.9 million and $1.2 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, 2021, the Company also had federal orphan drug credit carryforwards of approximately $1.0 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.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES" Act) was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits net operating loss carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows net operating losses incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. As the Company operated as a partnership during the carryback period, net operating loss carrybacks will not be allowed. Due to the Company's history of net operating losses, other provisions of the CARES Act are not expected to have a material impact on the Company's financial statements.

Pursuant to the Paycheck Protection Program (the "PPP") of the CARES Act, the Company received a PPP loan in the amount of $0.7 million. In 2021, the Company received forgiveness of the PPP loan. The loan forgiveness income is not considered taxable for Federal or state income tax purposes. In accordance with the Consolidated Appropriations Act, 2021 (CAA) enacted on December 27, 2020, certain qualified expenses used with the funds of the PPP Loan are fully deductible for Federal income tax purposes; however, California does not conform to this aspect of the CAA.

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 guidance 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.

The following table summarizes the reconciliation of the unrecognized tax benefits activity during the year ended December 31, 2021 (in thousands):

Balance as of December 31, 2019	$	—
Gross increase – current-period tax positions		210
Balance as of December 31, 2020	$	210
Gross increase – current-period tax positions		801
Balance as of December 31, 2021	$	1,011

As of December 31, 2021, the Company had gross unrecognized tax benefits of approximately $1.0 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 consolidated balance sheet and has not recognized interest or penalties in the consolidated statements of net and comprehensive income for the year ended December 31, 2021. 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 2018 and 2017, respectively, and forward. However, any adjustment made for the period prior to the conversion to C Corporation in July 2020 would be passed through to the Company's former members. Post-conversion to C Corporation, 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.

14. Subsequent events

The Company has completed an evaluation of all subsequent events through February 28, 2022 for the financial statements as of and for the year ended December 31, 2021 to ensure these consolidated financial statements include appropriate disclosure of events both recognized in the consolidated financial statements and events which occurred but were not recognized in the consolidated financial statements. Except as described below or elsewhere in these consolidated financial statements, the Company has concluded that no subsequent event has occurred that requires disclosure.

On January 5, 2022, BioAtla 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, BA3011 and 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. There was no impact to the Company's financial results for the year ended December 31, 2021 as a result of this agreement.

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, 2021. 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, 2021, 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, 2021, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. Our independent registered public accounting firm, Ernst & Young LLP, has issued an audit report with respect to our internal control over financial reporting, which is included herein.

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 2021 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We are continually monitoring and assessing the COVID-19 situation on our internal controls to understand the potential impact on their design and operating effectiveness.

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 and the Report of Independent Registered Public Accounting Firm on our internal control over financial reporting herein.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited BioAtla, Inc.'s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, BioAtla, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of BioAtla, Inc. as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders'/members' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated February 28, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP
San Diego, California
February 28, 2022

ITEM 9B. Other Information

None.

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 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 consolidated 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

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	12-18-20	
3.2	Amended and Restated Bylaws of BioAtla, Inc.	8-K	001-39787	3.2	12-18-20	
4.1	Specimen Common Stock Certificate evidencing the shares of common stock	S-1/A	333-250093	4.1	12-08-20	
4.2	Investors' Rights Agreement, dated July 13, 2020	S-1/A	333-250093	4.2	12-08-20	
4.3	Description of Securities					X
10.1+	2020 Equity Incentive Plan	S-1/A	333-250093	10.1	12-08-20	
10.2+	Amendment No. 1 to 2020 Equity Incentive Plan	S-8	333-251520	99.2	12-18-20	
10.3+	Form of Restricted Stock Agreement	S-1/A	333-250093	10.2	12-08-20	
10.4+	2020 Employee Stock Purchase Plan	S-1/A	333-250093	10.3	12-08-20	
10.5*	Exclusive License Agreement with Himalaya SEZC, dated January 1, 2020	S-1	333-250093	10.4	11-13-2020	
10.6*	Exclusive License Agreement with Inversagen LLC, dated March 15, 2019, as amended by First Amendment to Exclusive License Agreement, dated July 7, 2020	S-1	333-250093	10.5	11-13-2020	
10.7*	Exclusive License Agreement with BioAtla Holdings LLC, dated January 1, 2020, as amended by First Amendment to Exclusive License agreement, dated July 7, 2020	S-1	333-250093	10.6	11-13-2020	
10.8*	Amended and Restated Exclusive License Agreement with EXUMA Biotech Corp. (formerly F1 Oncology, Inc.), dated November 22, 2019	S-1	333-250093	10.7	11-13-2020	
10.9*	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	
10.10*	Cell Line License Agreement with Life Technologies Corporation, dated June 28, 2018	S-1	333-250093	10.9	11-13-2020	
10.11	Royalty Sharing Agreement with BioAtla Holdings, LLC, dated January 1, 2020	S-1	333-250093	10.10	11-13-2020	
10.12+	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	12-08-20	
10.13+	Offer Letter between BioAtla, LLC and Carolyn Short, dated November 30, 2015	S-1/A	333-250093	10.12	12-08-20	
10.14+	Severance Agreement between BioAtla, LLC and Jay Short, dated July 1, 2018	S-1/A	333-250093	10.13	12-08-20	
10.15+	Offer Letter between BioAtla, LLC and Scott Smith, dated August 2, 2018	S-1/A	333-250093	10.14	12-08-20	
10.16+	Letter Agreement between BioAtla, LLC and Scott Smith, dated August 3, 2018	S-1/A	333-250093	10.15	12-08-20	
10.17+	Severance Agreement between BioAtla, LLC and Scott Smith, dated August 20, 2018	S-1/A	333-250093	10.16	12-08-20	
10.18+	Severance Agreement between BioAtla, LLC and Carolyn Short, as amended by the Amended Severance Agreement between BioAtla, LLC and Carolyn Short, dated April 1, 2020	S-1/A	333-250093	10.17	12-08-20	
10.19+	Offer Letter between BioAtla, LLC and Richard Waldron, dated October 23, 2013					X
10.20+	Severance Agreement between BioAtla, LLC and Richard Waldron, dated July 1, 2018					X

Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Exhibit Filing Date	Filed/Furnished Herewith
10.21+	Offer Letter between BioAtla, LLC and Eric Sievers, dated June 17, 2019					X
10.22+	Offer Letter between BioAtla, LLC and Christian Vasquez, dated October 22, 2015					X
10.23+	Form of Indemnification Agreement between the Registrant and each of its executive officers	S-1/A	333-250093	10.18	12-08-20	
10.24	Lease Agreement with HCP Torreyana, LLC, dated June 2, 2017, as amended by First Amendment to Lease, dated January 16, 2019	S-1/A	333-250093	10.19	12-08-20	
10.25	Payment Protection Program Promissory Note dated April 22, 2020, by and between BioAtla, LLC and City National Bank.	S-1	333-250093	10.20	11-13-2020	
10.26	Amendment No. 2 to 2020 Equity Incentive Plan					X
10.27	Amendment No. 1 to Employee Share Purchase Plan					X
10.28*	Amendment No. 3 to Global Co-Development and Collaboration Agreement between BioAtla, Inc. and BeiGene, Ltd					X
10.29+	Form of Non-Employee Director Stock Option Agreement	10-Q	001-39787	10.1	11-15-2021	
10.30+	Form of Employee Stock Option Agreement	10-Q	001-39787	10.2	11-15-2021	
10.31+	BioAtla Director Compensation Policy					X
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
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 Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					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: February 28, 2022

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)*	February 28, 2022
/s/ Richard A. Waldron Richard A. Waldron	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 28, 2022
/s/ Scott Smith Scott Smith	President and Director	February 28, 2022
/s/ Guy Levy Guy Levy	Director	February 28, 2022
/s/ Lawrence Steinman Lawrence Steinman	Director	February 28, 2022
/s/ Mary Ann Gray, Ph.D. Mary Ann Gray, Ph.D.	Director	February 28, 2022
/s/ Susan Moran, M.D. Susan Moran, M.D.	Director	February 28, 2022
/s/ Sylvia McBrinn Sylvia McBrinn	Director	February 28, 2022
/s/ Edward Williams Edward Williams	Director	February 28, 2022