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, 2020

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-38582

Allakos Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**45-4798831**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
975 Island Drive, Suite 201 Redwood City, California	**94065**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 597-5002

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, par value $0.001	ALLK	The Nasdaq Global Select Market

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

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

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

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

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

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

Large accelerated filer	☒	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 Exchange Act). YES ☐ NO ☒

The aggregate market value of the common stock held by non-affiliates of the Registrant based on the closing price of the Registrant's Common Stock on the Nasdaq Global Select Market as of June 30, 2020 was $2,155.5 million.

The number of shares of Registrant's Common Stock outstanding as of February 23, 2021 was 53,117,414.

Portions of the Registrant's Definitive Proxy Statement relating to the registrant's 2020 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's 2020 fiscal year ended December 31, 2020.

Table of Contents

PART I

Item 1. Business.

Overview

We are a clinical stage biotechnology company developing lirentelimab (AK002), our wholly owned monoclonal antibody, for the treatment of various mast cell and eosinophil related diseases. Lirentelimab selectively targets both mast cells and eosinophils, two types of white blood cells that are widely distributed in the body and play a central role in the inflammatory response. Inappropriately activated mast cells and eosinophils have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. Our initial focus is on eosinophilic gastrointestinal diseases which include eosinophilic gastritis ("EG"), eosinophilic duodenitis ("EoD") which has also been referred to as eosinophilic gastroenteritis, and eosinophilic esophagitis ("EoE"); in addition, lirentelimab has the potential to treat a number of other severe diseases. Lirentelimab has received orphan disease status for EG, EoD, and EoE from the U.S. Food and Drug Administration (the "FDA"). Lirentelimab completed a randomized, double-blind, placebo-controlled Phase 2 study in patients with EG and/or EoD (see ENIGMA study results). The ENIGMA study met all prespecified primary and secondary endpoints when compared to placebo and results were published in the New England Journal of Medicine. ENIGMA patients that continued to receive lirentelimab treatment for at least 52 weeks have experienced continued symptom improvement with an average 70% reduction in EG and EoD symptoms. Additionally, patients in the ENIGMA study with co-morbid EoE showed histologic and symptomatic improvement when treated with lirentelimab compared to placebo. Based on the results from the ENIGMA study and End of Phase 2 meeting with the FDA, we began enrollment of a Phase 3 study in patients with EG and/or EoD and a Phase 2/3 study in patients with EoE. We expect results from these trials in the fourth quarter of 2021.

Despite the knowledge that mast cells and eosinophils drive many pathological conditions, there are no approved therapies that selectively target both mast cells and eosinophils. Lirentelimab binds to Siglec-8, an inhibitory receptor found on mast cells and eosinophils, which represents a novel mechanism to selectively inhibit or deplete these important immune cells and thereby potentially resolve inflammation. We believe lirentelimab is the only Siglec-8 targeting antibody currently in clinical development and may have advantages over current treatment options available to patients for the diseases we are pursuing.

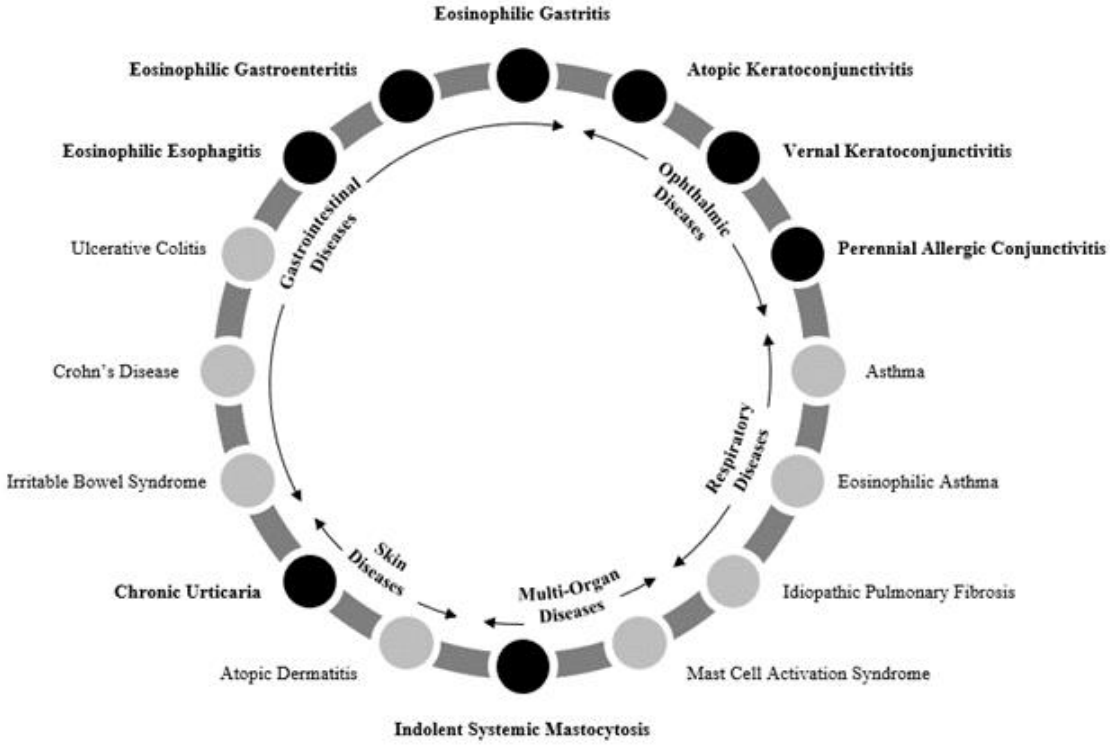
Our lead indication is EG and/or EoD, which are chronic, often severe, inflammatory diseases characterized by persistent gastrointestinal symptoms and elevated and activated eosinophils in the stomach and/or, duodenum, respectively. Emerging data suggests that activated mast cells also contribute to disease pathogenesis. Common symptoms of the diseases include abdominal pain, nausea, diarrhea, bloating, cramping, early satiety, loss of appetite, vomiting and weight loss. There are no treatments approved specifically for these diseases. Treatment with systemic steroids can provide symptomatic improvement, but long-term treatment with steroids is generally not possible due to the numerous side effects. Published literature reports the prevalence of EG and EoD in the United States to be approximately 50,000 people. However, we believe that these diseases may be significantly underdiagnosed or misdiagnosed as other gastrointestinal diseases.

Initial evidence of underdiagnosis came from the ENIGMA study. During the enrollment phase of the ENIGMA study, our investigational sites screened patients that had not been previously diagnosed with EG or EoD. Many of these patients had chronic unexplained gastrointestinal symptoms or had been previously diagnosed with a functional gastrointestinal disorder ("FGID") such as irritable bowel syndrome ("IBS") and functional dyspepsia ("FD"). Of 26 patients biopsied with no prior EG or EoD diagnosis, 15 (58%) were found to have EG or EoD and were therefore eligible for enrollment in the ENGIMA study. The high rate of discovery among previously undiagnosed patients suggested that many patients with chronic gastrointestinal symptoms (including those diagnosed with IBS, FD or nonspecific gastritis) have EG and/or EoD. More recently, we have confirmed these findings in a large prospective study examining the rates of elevated eosinophil and mast cell levels in patients with chronic unexplained gastrointestinal symptoms or FGIDs such as IBS and FD. In this prevalence study 45% (181 of 405) of patients biopsied met the histologic criteria for EG and/or EoD (See Prevalence Study results for more information). Millions of patients in the U.S. are under the care of a gastroenterologist and suffer from chronic unexplained gastrointestinal symptoms or FGIDs. Our results provide evidence that prevalence of EG and EoD is significantly higher than reported in the literature.

Our other late-stage trial is in EoE, a severe orphan gastrointestinal disease characterized by dysphagia (difficulty swallowing) resulting from inflammation caused by elevated and inappropriately activated mast cells and eosinophils. Lirentelimab has received orphan drug designation for EoE from the FDA. The estimated prevalence of EoE in the United States is approximately 150,000-200,000 patients and there are no treatments currently approved specifically for this disease.

Lirentelimab also showed promising activity in clinical studies in chronic urticaria ("CU", see Chronic Urticarias for clinical results), indolent systemic mastocytosis ("ISM", see Indolent Systemic Mastocytosis for clinical results), severe allergic conjunctivitis ("SAC", see severe allergic conjunctivitis for clinical results), and mast cell gastrointestinal disease ("MGID", see mast cell gastritis clinical results). In addition, patients in clinical studies with atopic comorbidities such as asthma, atopic dermatitis, and allergic rhinitis experienced improvements in these conditions. The activity observed in these studies suggests that lirentelimab could provide significant benefit to patients suffering from these diseases and highlights the potential of lirentelimab to broadly inhibit mast cells and deplete eosinophils in different disease settings.

Figure 1: Potential lirentelimab clinical indications, indications with completed studies shown in bold



To date, lirentelimab has been administered intravenously in our clinical efficacy studies. Lirentelimab has generally been well-tolerated in each of our clinical trials. The most common adverse event with intravenous lirentelimab has been the occurrence of mild to moderate infusion related reactions, consisting of flushing, feeling of warmth, headache, nausea or dizziness, which occurred mostly during the first infusion and diminished or did not occur on subsequent infusions. We also have developed a formulation of lirentelimab for subcutaneous ("SC") administration and have completed a Phase 1 study in healthy volunteers evaluating the safety, tolerability and pharmacokinetics of SC lirentelimab (for additional information, see "Lirentelimab Clinical Development–*Subcutaneous Lirentelimab*"). SC lirentelimab provided prolonged eosinophil depletion supporting monthly administration and was well tolerated; there were no serious adverse events, no injection site reactions, and no injection-related reactions.

Lirentelimab efficacy and proof of concept studies are listed in Figure 2 below. See "*Lirentelimab Clinical Development*" for further detail on these studies.

Figure 2. Lirentelimab Efficacy and Proof of Concept Studies

Study	Milestone
Phase 3 Eosinophilic Gastritis and/or Duodenitis	Data Expected Q4 2021
Phase 2/3 Eosinophilic Esophagitis	Data Expected Q4 2021
Phase 3 Eosinophilic Duodenitis	Initiation Expected Q2 2021
Phase 2/3 SC Lirentelimab Eosinophilic Gastritis and/or Duodenitis	Initiation Expected H2 2021
Phase 1 Mast Cell Gastrointestinal Disease	Completed 2020
Phase 2 Eosinophilic Gastritis and/or Duodenitis	Completed 2019
Phase 2 Chronic Urticaria	Completed 2019
Phase 1 Severe Allergic Conjunctivitis	Completed 2019
Phase 1 Indolent Systemic Mastocytosis	Completed 2019

Understanding the Foundation of Our Approach

Background on Mast Cells, Eosinophils and Siglec-8

Mast cells and eosinophils are involved in many inflammatory conditions and therefore represent attractive drug targets. Mast cells and eosinophils can respond to signals from allergens, tissues, bacteria, viruses and also cells of the innate and adaptive immune system. In response, they release a large variety of mediators which can result in tissue damage, fibrosis and the recruitment and activation of other innate and adaptive immune cells. The ability to respond to signals from multiple cell types and the diverse array of mediators that they produce place mast cells and eosinophils in the center of multiple aspects of the inflammatory response.

Eosinophils are normally present in the blood and tissues, especially in the mucosal linings of the respiratory and lower gastrointestinal tract. However, they can be recruited to any site of the body in the setting of inflammation. Mast cells reside within tissues and all vascularized organs, often located in close proximity to blood vessels, nerves and lymphatics. Sites include the dermis, gut mucosa and submucosa, conjunctiva and pulmonary alveoli and airways. As a result of their widespread location and potent inflammatory activity, mast cells and eosinophils have been identified as key drivers in a number of severe diseases of the gastrointestinal tract, eyes, skin and lungs as well as diseases which affect multiple organ systems.

Siglec-8 is an inhibitory receptor selectively expressed on eosinophils, mast cells and, to a lesser extent, on basophils. Because Siglec-8 is expressed in high abundance only on mast cells and eosinophils, it presents a novel way to selectively target these important immune cells. As an inhibitory receptor, the natural function of Siglec-8 is to counteract activating signals within mast cells and eosinophils that lead to an inflammatory response. By binding to Siglec-8, lirentelimab is able to selectively target mast cells and eosinophils to resolve inflammation.

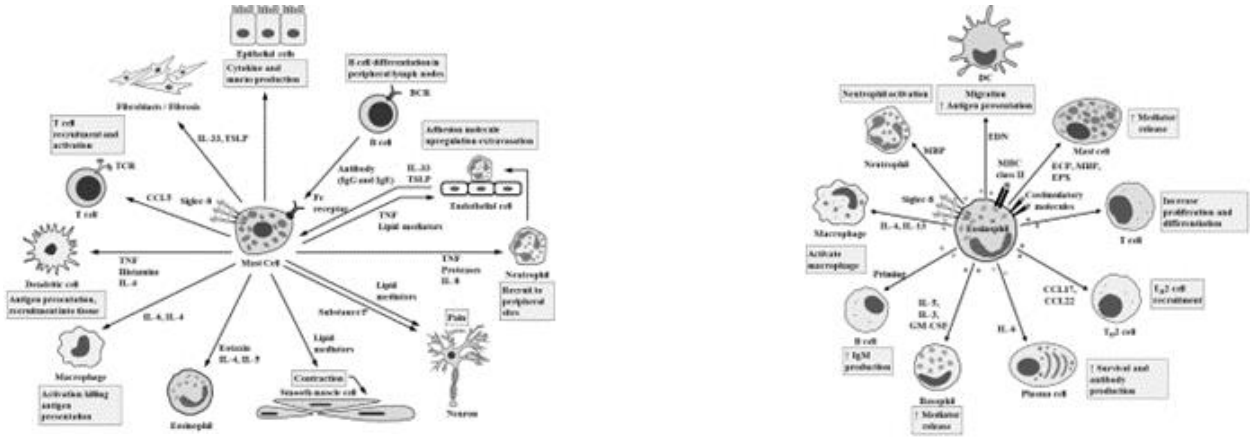
Mast cells and Eosinophils are Effector Cells That are Central to Initiating and Maintaining Inflammatory Responses

Mast cells and/or eosinophils respond to a variety of activating signals including those from cell-cell contact, allergens bound to IgE, neuropeptides (such as Substance P), cytokines including IL-33, thymic stromal lymphopoietin ("TSLP"), IL-5, IL-4 and IL-13 and viruses through Toll-Like Receptor-3. In response to these and other activating signals, mast cells and eosinophils produce a broad range of inflammatory mediators that cause tissue damage and contribute to acute and chronic inflammation. These mediators include vasoactive amines, bioactive lipids, proteases, chemokines and cytokines. The mediators, their functions and their contribution to disease pathogenesis are described in more detail below.

- *Mast cells play an important role in inflammation as the main producer of histamine.* Histamine causes vasodilation and produces intense itching. It is believed to contribute to increased gastrointestinal peristalsis (diarrhea), the skin symptoms of urticaria and ISM, the diffuse vasodilation of anaphylaxis and bronchospasm in asthma.

- *Proteases secreted from mast cells and eosinophils are the key cause of tissue damage and contribute to tissue fibrosis.* Eosinophil and mast cell secretions are toxic to surrounding cells and break down tissues, resulting in fibrosis and tissue remodeling.
- *Mast cells and eosinophils drive inflammation by signaling to other cells of the immune system.* Mast cells and eosinophils release lipid mediators and a large variety of cytokines including TNFa, IL-1, IL-3, IL-4, IL-5, IL-6, IL-8, IL-9, IL-13, MCP-1, CCL2, CCL3, CCL5, CCL17, TGFa, TGFb and granulocyte-macrophage colony stimulating factor, that attract and activate cells of the innate and adaptive immune system, such as neutrophils, monocytes, macrophages, basophils, B-cells, T-cells and dendritic cells, as well as other mast cells and eosinophils.

Figure 3. Mast Cell and Eosinophil Functions

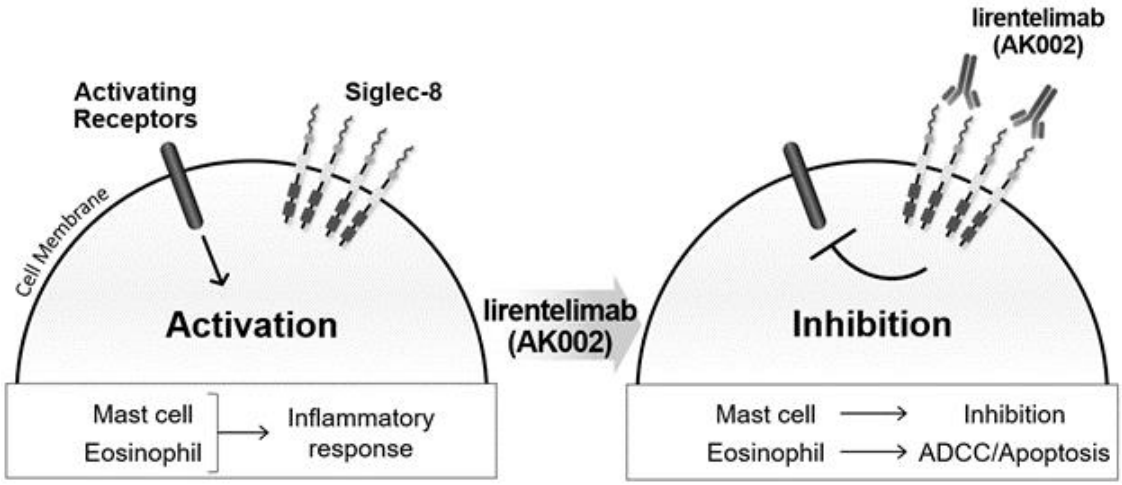


Due to their ability to respond to signals from multiple cell types and elicit responses from others, mast cells and eosinophils mediate the immediate hypersensitivity and late phase responses responsible for allergies and many innate and adaptive immune responses.

Siglec-8 is an Attractive Target for Mast Cell and Eosinophil Driven Diseases

Siglec-8 (sialic acid immunoglobulin-like lectin 8) is a constitutively expressed inhibitory receptor that is restricted to eosinophils, mast cells and to a lesser extent, basophils (approximately 1/100 the level on mast cells and eosinophils). The physiological function of Siglec-8 is to provide an inhibitory signal to mast cells and eosinophils. Siglec-8 exerts these effects through an intracellular immunoreceptor tyrosine-based inhibitory motif ("ITIM") and ITIM-like motif. In contrast to approaches which block a single activating cytokine or receptor, targeting the ITIM signaling cascade (via Siglec-8) has the potential to counteract a broad array of activating signals, which could allow for the treatment of multiple diseases. Antibodies to Siglec-8 have been shown to trigger antibody-dependent cellular cytotoxicity ("ADCC") of blood eosinophils and apoptosis of tissue eosinophils and to inhibit the release of inflammatory mediators from mast cells. In the human clinical studies, lirentelimab has depleted eosinophils and demonstrated mast cell inhibitory activity in multiple disease settings including EG, EoD, EoE, CU, SAC, and ISM. In summary, the expression pattern and broad inhibitory function make Siglec-8 an attractive target for treatment of mast cell and eosinophil driven diseases.

Figure 4. Siglec-8 Triggers Apoptosis of Eosinophils and Inhibition of Mast Cells



Our Strategy

Lirentelimab has shown activity in humans as well as activity in a broad array of animal disease models of mast cell and eosinophil driven diseases. We have prioritized our lirentelimab development efforts based on our assessment of the probability of clinical and regulatory success, unmet medical need and potential market opportunity. We have assembled a team with a proven track record and deep experience in antibody discovery and in clinical development, commercialization, operations and finance from companies such as Genentech, Gilead, Intermune, Novo Nordisk, Pfizer, ZS Pharma and others.

The key elements of our strategy are to:

- ***Rapidly advance lirentelimab through clinical development in EG, EoD and EoE.*** Lirentelimab has secured orphan drug designation for the treatment of EG and EoD from the FDA. We believe the positive results from our Phase 2 ENIGMA study in patients with EG and/or EoD, in conjunction with our Phase 3 study, will serve as the basis for demonstrating safety and efficacy in our biologics license application ("BLA") and market authorization application submissions. Lirentelimab has secured orphan drug designation for the treatment of EoE from the FDA. We are conducting a Phase 2/3 study in patients with EoE and expect results in Q4 2021.
- ***Evaluate additional eosinophilic and mast cell driven conditions.*** We have completed trials in patients with MGID, CU, ISM, and SAC and will continue to evaluate commercial opportunities in these, as well as other indications.
- ***Build commercial capability and retain rights in key markets.*** We intend to retain the rights to lirentelimab in key markets for the time being, and plan to commercialize lirentelimab in the U.S through a specialty sales force.

Lirentelimab Clinical Development

Lirentelimab was designed to take advantage of the selective expression pattern and inhibitory function of Siglec-8, an inhibitory receptor found on eosinophils, mast cells, and to a lesser extent, on basophils. Lirentelimab is a humanized antibody that binds to Siglec-8 with high affinity (bivalent binding avidity KD = 17 pM, determined by surface plasmon resonance analysis). Binding of lirentelimab to Siglec-8 on mast cells and eosinophils triggers apoptosis of eosinophils and inhibition of mast cells. Lirentelimab is a non-fucosylated IgG1 antibody engineered to have potent ADCC. ADCC is a mechanism whereby the binding of an antibody like lirentelimab to a target cell in the blood, such as an eosinophil, triggers a natural killer ("NK") cell, to bind to the Fc portion of the antibody bound to the target cell, thereby destroying the antibody-bound cell. This provides lirentelimab with an additional

mechanism to deplete eosinophils present in blood. As a result of these dual modes of action, lirentelimab has been shown to deplete eosinophils in blood and tissue, and to inhibit the release of inflammatory mediators from mast cells.

Lirentelimab has demonstrated activity in a broad array of animal disease models of eosinophilic and mast cell-driven diseases. Consistent with these experiments, human trials have shown that lirentelimab depletes blood eosinophils and inhibits mast cells in multiple different diseases including EG, EoD, EoE, CU, ISM, and SAC. Based on the promising results in the ENIGMA study, we have initiated a Phase 3 study in EG and/or EoD and a Phase 2/3 study in EoE, with the results of the studies expected in the fourth quarter of 2021. To date, lirentelimab has been administered intravenously in our clinical efficacy studies. Lirentelimab has generally been well-tolerated in each of our clinical trials. The most common adverse event with intravenous lirentelimab has been the occurrence of mild to moderate infusion related reactions, consisting of flushing, feeling of warmth, headache, nausea or dizziness, which occurred mostly during the first infusion and diminished or did not occur on subsequent infusions.

Subcutaneous Lirentelimab

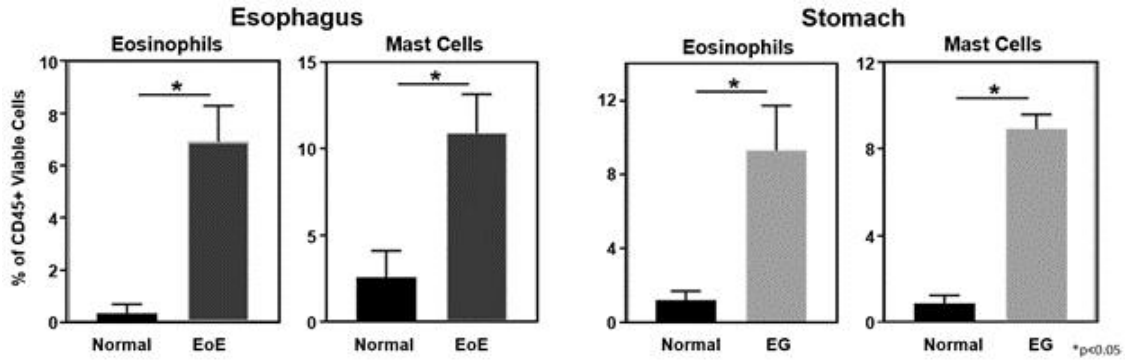
We also have developed a formulation of lirentelimab for subcutaneous administration and have completed a randomized, double-blind, placebo-controlled, single dose, dose ranging Phase 1 study in healthy volunteers evaluating the safety, tolerability and pharmacokinetics of SC lirentelimab. Bioavailability of SC lirentelimab was 63% and SC lirentelimab resulted in extended eosinophil suppression at all dose levels tested. At dose levels of 3.0 and 5.0 mg/kg and with the fixed dose of 300 mg, SC lirentelimab resulted in eosinophil suppression in all subjects through Day 85. The pharmacokinetic and pharmacodynamic results suggest that SC lirentelimab may be given monthly or potentially less frequently. SC lirentelimab was well tolerated, and there were no serious adverse events, no injection site reactions, and no injection-related reactions with SC lirentelimab.

Eosinophilic Gastrointestinal Diseases ("EGIDs")

EGIDs are a collection of chronic inflammatory disorders that share a similar eosinophilic driven inflammation that occurs along different segments of the gastrointestinal ("GI") tract. Based on the site of eosinophilic infiltration, EGIDs are categorized into EoE (esophagus), EG (stomach), EoD (duodenum), and eosinophilic colitis (colon). There are no treatments currently approved specifically for these diseases and lirentelimab has secured orphan drug designation for EG, EoD, and EoE from the FDA.

It is believed that EGIDs arise in some patients from food allergies or other allergens that cause a hypersensitivity reaction that leads to recruitment of eosinophils to the GI tract. Mast cells are also elevated and activated and are believed to play a significant role. The gastrointestinal symptoms are believed to be due to the release of inflammatory mediators from activated eosinophils and mast cells. Elevated serum immunoglobulin E ("IgE") levels and food-specific IgE are correlated with EG in some patients and provide evidence for the allergy hypothesis and mast cell involvement. We have recently demonstrated that in biopsies of patients with symptomatic EG, mast cells are present in elevated numbers compared to normal controls and that the mast cells are also in an increased activation state, providing additional evidence for a pathogenic role of mast cells in EGIDs.

Figure 5. Mast Cells and Eosinophils are Elevated in EGIDs



Because lirentelimab directly depletes eosinophils and broadly inhibits mast cells, we believe it has the potential to be a superior treatment in comparison to agents acting only on one cell type or pathway.

Eosinophilic Gastritis and Eosinophilic Duodenitis

EG and EoD are diseases characterized by chronic inflammation due to infiltration of eosinophils and mast cells into layers of the stomach and duodenum. Symptoms commonly include abdominal pain, nausea, vomiting, diarrhea, early satiety, loss of appetite, abdominal cramping, bloating, malnutrition and weight loss. EG and EoD can occur with eosinophilia isolated to the stomach or duodenum, or often in combination. Diagnosis is established based on clinical presentation (gastrointestinal symptoms) combined with increased tissue eosinophils in biopsy specimens from the stomach and/or duodenum without any other cause for the eosinophilia. The presence of greater than or equal to 30 eosinophils per high-powered field ("HPF") in 5 HPFs in the stomach indicates the presence of EG, and the presence of greater than or equal to 30 eosinophils per HPF in 3 HPFs in the duodenum indicates the presence of EoD. Based on ICD-9 codes, the prevalence of EG and EoD in the United States has previously been reported in the literature to be approximately 50,000 patients. However, we believe these diseases may be significantly under-diagnosed, or mis-diagnosed as other gastrointestinal diseases (such as irritable bowel syndrome or functional dyspepsia), based on observations from the ENIGMA study as well as results of a prevalence study we conducted to assess the prevalence of EG and EoD in patients with chronic gastrointestinal symptoms.

Eosinophilic Gastritis and Eosinophilic Duodenitis Prevalence Study

Initial evidence of underdiagnosis came from the ENIGMA study. During the enrollment phase of the ENIGMA study, our investigational sites screened patients that had not been previously diagnosed with EG or EoD. Many of these patients had chronic unexplained gastrointestinal symptoms or had been previously diagnosed with a functional gastrointestinal disorder ("FGID") such as irritable bowel syndrome ("IBS") and functional dyspepsia ("FD"). Of 26 patients biopsied with no prior EG or EoD diagnosis, 15 (58%) were found to have EG or EoD and were therefore eligible for enrollment in the ENGIMA study. The high rate of discovery among previously undiagnosed patients suggested that some patients with chronic gastrointestinal symptoms (including those with IBS, FD or nonspecific gastritis) have EG and/or EoD.

More recently, we have confirmed these findings in a prospective prevalence study examining the rates of elevated eosinophil and mast cell levels in 556 patients with chronic unexplained gastrointestinal symptoms or FGIDs such as IBS and FD. The prospective, multi-center study assessed eosinophil and mast cell levels in biopsies obtained from patients with active, chronic unexplained gastrointestinal symptoms or FGIDs. Inclusion in the study required patients to have ≥6-month history of abdominal pain, abdominal cramping, nausea, vomiting, diarrhea, bloating and/or early satiety without identifiable cause and unresponsive to pharmacologic or dietary intervention, or a diagnosis of IBS or FD. Gastric and duodenal biopsies were performed in patients who had an average weekly single symptom severity score ≥3 (on a 10 point scale) for abdominal pain, abdominal cramping, nausea, vomiting, diarrhea, bloating or early satiety and a total symptom severity score ≥10 as assessed by the patient reported outcome ("PRO") questionnaire used in our Phase 2 (ENIGMA) and Phase 3 EG and/or EoD studies.

In this study, 73% (405 of 556) of patients screened met the symptom severity criteria and underwent endoscopy with biopsy. Of the patients biopsied, 45% (181 of 405) met the histologic criteria for EG and/or EoD (≥30 eosinophils/HPF in 5 HPFs of the stomach and/or ≥30 eosinophils/HPF in 3 HPFs of the duodenum, respectively), representing 33% (181 of 556) of patients screened. Since millions of people in the United States and worldwide suffer from chronic unexplained gastrointestinal symptoms or FGIDs, the results from these studies suggest that EG and/or EoD may be more common than previously documented in the literature.

Eosinophilic Esophagitis

EoE is an orphan disease characterized by eosinophil and mast cell driven inflammation of the esophagus. Common symptoms of EoE include dysphagia (difficulty swallowing), food impaction, nausea and vomiting. Diagnosis is established based on clinical presentation (dysphagia) combined with increased tissue eosinophils in biopsy specimens from the esophagus without any other cause for the eosinophilia. The presence of greater than 15 eosinophils per HPF in an esophageal biopsy identifies the presence of EoE. The estimated prevalence of EoE in the United States is approximately 200,000 patients.

Current Therapies and Limitations

There are no FDA-approved treatments for EG, EoD or EoE. Current therapies and disease management strategies include restricted/elemental diets and systemic or topical corticosteroids. Restricted/elemental diets are designed to avoid foods which trigger symptoms. Unfortunately for most patients the restricted/elemental diets are only partially effective and mainly used as a strategy to provide nutrition despite continuing symptoms. Corticosteroids, systemic or topical, can provide symptom relief, but are not appropriate for long-term treatment due to their numerous side effects.

ENIGMA Study: Phase 2 Study in Patients with EG and/or EoD

Study Design

The ENIGMA study, a randomized, double-blind, placebo-controlled Phase 2 study of lirentelimab enrolled patients with active, biopsy-confirmed EG and/or EoD. Patients were required to be moderately to severely symptomatic based on a patient reported symptom questionnaire and to subsequently have biopsy confirmed eosinophilia of the stomach (≥ 30 eosinophils/HPF in 5 HPFs) and/or duodenum (≥ 30 eosinophils/HPF in 3 HPFs). Qualifying patients were randomized 1:1:1 to receive: (a) 0.3 mg/kg of lirentelimab for the first month followed by three doses of 1.0 mg/kg given monthly, (b) 0.3 mg/kg of lirentelimab for the first month followed by 1.0 mg/kg, 3.0 mg/kg and 3.0 mg/kg given monthly, or (c) a monthly placebo. Disease symptoms were measured daily using a patient reported symptom questionnaire that scored 8 symptoms on a scale from 0 to 10 (abdominal pain, nausea, vomiting, early satiety, loss of appetite, abdominal cramping, bloating, and diarrhea). Endpoints were assessed per protocol in a prespecified hierarchical order using biopsies collected at the end of study and symptom questionnaires collected over the last two weeks of study prior to biopsy. The primary endpoint was the percent change from baseline in the number of tissue eosinophils obtained from gastric or duodenal biopsies. The secondary endpoints were (1) proportion of patients with a greater than 75% reduction in tissue eosinophil counts from biopsies and a greater than 30% reduction in Total Symptom Score (“TSS”) from the patient reported questionnaire and (2) the percent change from baseline in the TSS.

Study Results

Lirentelimab showed a statistically significant benefit when compared to placebo on all primary and secondary endpoints for each of the high dose, low dose, and combined high/low dose lirentelimab groups. The data demonstrate that lirentelimab produced histological resolution of gastrointestinal tissue eosinophilia and improved disease symptoms, and that these benefits occurred in the same individuals. Results from this study were recently published in the New England Journal of Medicine.

Figure 6: Topline results from the ENIGMA study

Primary and Secondary Endpoints	Placebo (n=20)	High Dose lirentelimab (n=20)	Low Dose lirentelimab (n=19)	Combined lirentelimab (n=39)
1° Endpoint: change in gastric or duodenal eosinophil counts	+10%	-97%	-92%	-95%
p–value	—	<0.0001	<0.0001	<0.0001
2° Endpoint: treatment responders [1]	5%	70%	68%	69%
p–value	—	0.0009	0.0019	0.0008
2° Endpoint: change in TSS [2]	-24%	-58%	-49%	-53%
p–value	—	0.0012	0.0150	0.0012

1 Treatment responders defined as patients with greater than a 75% reduction in biopsy eosinophil counts and a greater than 30% reduction in TSS.

2 TSS is the sum of all 8 patient reported symptoms each measured on a scale from 0 to 10 (abdominal pain, nausea, vomiting, early satiety, loss of appetite, abdominal cramping, bloating, and diarrhea).

Safety

Lirentelimab was generally well tolerated. The only treatment emergent adverse event occurring more frequently on lirentelimab than on placebo was mild to moderate IRRs, such as flushing, feeling of warmth, headache, nausea, and/or dizziness, which occurred in 60% of patients receiving lirentelimab versus 23% of patients receiving placebo. There was 1 drug-related serious adverse event (“SAE”) in the study, consisting of an IRR that resolved within 24 hours. Treatment emergent SAEs occurred in 9% of patients receiving lirentelimab versus 14% of patients receiving placebo.

Results in Patients with EoE

Esophageal eosinophil counts and dysphagia improved in patients with comorbid eosinophilic esophagitis.

Figure 7: EoE endpoints from the ENIGMA study

Exploratory Endpoints	Placebo	Combined lirentelimab
EoE: proportion of patients with esophageal eosinophil counts <5/HPF	1/9 (11%)	13/14 (93%)
EoE: change in patient reported dysphagia questionnaire	-17%	-53%

Steroid Use

All allowed baseline medications remained constant throughout the baseline period and study. Acute steroids could be used at the physician’s discretion to prevent or treat IRRs. Acute steroid use was balanced between lirentelimab and placebo groups with 28% and 35% of patients in the lirentelimab and placebo group receiving acute steroids, respectively. Statistically significant results were also observed on all primary and secondary endpoints in the subgroup of patients who did not receive acute steroids.

Long-Term Extension Study

Ninety-two percent of eligible patients from the ENIGMA study elected to enter a long-term extension study. These patients have reported further disease symptom improvement with continued lirentelimab treatment. For example, in EG and/or EoD patients with at least 52 weeks of lirentelimab treatment, mean total symptom scores were reduced 70%.

In the long-term extension study, we evaluated the effect of pre-treating patients with oral prednisone one day prior to receiving a 1.0 mg/kg first dose of lirentelimab. This evaluation included lirentelimab naïve patients receiving an initial 1.0 mg/kg of lirentelimab. No IRRs were observed in patients pre-treated with prednisone the day prior to receiving lirentelimab despite using a higher initial dose than the 0.3 mg/kg dose used in the ENIGMA

study. These results suggest prednisone may be a useful pre-treatment to reduce or eliminate IRRs in future studies of lirentelimab.

Current and Future Studies

Lirentelimab has secured orphan drug designation for EG, EoD, and EoE from the FDA. Based on the promising results from the ENIGMA study, we have initiated a Phase 3 study in patients with EG and/or EoD and a Phase 2/3 study in patients EoE. We expect results from both of these studies in Q4 2021. Based on communications with the FDA, we believe the results of the ENGIMA study, in conjunction with the results from the Phase 3 study, if successful, will be sufficient for regulatory approval. We plan to initiate a Phase 3 study in patients with EoD without EG in Q2 2021. In this study, in addition to the duodenum, we plan to examine eosinophil and mast cell levels in the terminal ileum and colon before and after lirentelimab treatment. Evaluation of the terminal ileum and colon will help characterize EoD patients and could provide insights for further development of lirentelimab in colonic conditions such as eosinophilic colitis and ulcerative colitis. We also plan to initiate a Phase 2/3 study of fixed doses of monthly SC lirentelimab in patients with EG and/or EoD in H2 of 2021.

Figure 8. Ongoing and Planned Lirentelimab EG, EoD, and EoE Clinical Studies

Study	Milestone
Phase 3 Eosinophilic Gastritis and/or Duodenitis	Data Expected Q4 2021
Phase 2/3 Eosinophilic Esophagitis	Data Expected Q4 2021
Phase 3 Eosinophilic Duodenitis	Initiation Expected Q2 2021
Phase 2/3 SC Lirentelimab Eosinophilic Gastritis and/or Duodenitis	Initiation Expected H2 2021

Mast Cell Gastrointestinal Disease

During the enrollment phase of the ENIGMA study, we identified a group of patients who were symptomatic but upon biopsy had ≥ 30 stomach and/or duodenal mast cell counts in the absence of elevated eosinophils (<30 eosinophils/HPF). The presence of elevated mast cell counts and lack of elevated eosinophils or other cell type suggests that these patients may suffer from mast cell driven gastrointestinal symptoms. We refer to this condition as Mast Cell Gastrointestinal Disease (“MGID”). As detailed above, we conducted a prospective prevalence study examining the rates of elevated eosinophil and mast cell levels in 556 patients with chronic unexplained gastrointestinal symptoms or FGIDs such as IBS and FD. 73% (405 of 556) of patients screened underwent endoscopy with biopsy. Of the patients biopsied, 50% (204 of 405) met the histologic criteria for MGID, representing 37% (204 of 556) of patients screened. The results suggest that a large number of patients meet the criteria we established for MGID.

We have conducted a proof of concept Phase 1 study with lirentelimab in patients with MGID. The open-label, multi-dose, 6-month, Phase 1 study of lirentelimab consisted of seven patients with moderate to severe gastrointestinal symptoms and elevated mast cells (≥30 mast cells/HPF in at least 5 HPFs in the stomach and/or ≥30 mast cells/HPF in at least 3 HPFs in the duodenum) who did not have >30 eosinophils/HPF. Patients received 0.3 mg/kg of lirentelimab for the first dose, followed by 1.0 mg/kg the following month, then monthly doses of 3.0 mg/kg for four additional months. Disease symptoms were assessed using the patient reported outcome (“PRO”) questionnaire used in our Phase 2 (ENIGMA) and Phase 3 EG and/or EoD studies (Total Symptom Score TSS-8: abdominal pain, nausea, vomiting, early satiety, loss of appetite, abdominal cramping, bloating, and diarrhea). Six-month treatment with lirentelimab resulted in a 64% mean reduction in TSS-8 compared to baseline and five of seven (71%) patients had >50% reduction in TSS-8. The treatment effect of lirentelimab in this open label study was similar to that observed with lirentelimab in patients with EG and/or EoD in the Phase 2 ENIGMA Study.

Chronic Urticarias

Disease Overview

CU is a group of mast cell driven skin conditions which are characterized by recurrent transient pruritic wheal and flare type skin reactions and, in roughly 40% of patients, angioedema. Symptoms include hives, itching, redness, burning, warmth, tingling and irritation of the skin. Patients with CU are often severely impaired in their

quality of life, with negative effects on sleep, daily activities, school/work life and social interactions. Urticaria symptoms are caused by degranulation of dermal mast cells, with IgE signaling believed to contribute to mast cell activation in many cases. The most common forms of CU are chronic spontaneous urticaria ("CSU"), cholinergic urticaria and symptomatic dermatographism.

Despite sharing similar inflammatory pathology, the various forms of urticaria differ in the triggers that elicit the inflammatory response and symptoms. Patients with cholinergic urticaria typically develop symptoms a few minutes after exercise or passive warming in a bath or shower. In some cholinergic patients, emotional stress or hot and spicy food or beverages can also elicit symptoms. Symptomatic dermatographism is characterized by hives and pruritis following ~~a~~ minor stroking pressure, rubbing or scratching of the skin. In CSU, pruritic wheal-and-flare-type skin reactions spontaneously appear on the skin at any time of the day or night. In most CSU patients, an underlying cause of CSU cannot be identified making a causal and/or curative treatment difficult. We estimate that approximately 200,000-500,000 patients with severe CSU, cholinergic urticaria and symptomatic dermatographism could be candidates for therapy with lirentelimab in the United States.

Current Therapies and Limitations

The current treatment guidelines for the management of all forms of urticaria recommend the use of non-sedating oral H1-antihistamines as first-line therapy. For patients who do not respond to standard doses of H1-antihistamines, doses are increased to as high as four times the standard dose. Though this can increase the response rates, side effects also increase, including sedation and anticholinergic effects, such as dry mouth, blurred vision, urinary retention and constipation. Patients who do not respond to or are unable to tolerate high dose antihistamines have few options. For cholinergic urticaria and symptomatic dermatographism patients, it is recommended that they avoid target triggers such as overheated spaces, hot baths/showers, exercise, specific food allergens and excessive contact. For antihistamine refractory patients with CSU, the only currently approved treatment is Xolair, a monoclonal anti-IgE antibody. Unfortunately, approximately 60% of CSU patients continue to have symptoms despite treatment with Xolair.

Phase 2 Study Design and Results

We conducted an open-label Phase 2 study with lirentelimab in patients with uncontrolled CU despite treatment with H1 antihistamines at up to 4x the labeled dose. The study enrolled four cohorts consisting of 13 Xolair naïve patients with CSU, 11 Xolair refractory patients with CSU (average duration of Xolair treatment 10 months at doses as high as 600mg/month), 11 patients with cholinergic urticaria, and 10 patients with symptomatic dermographism. Baseline symptom scores, as measured by Urticaria Control Test ("UCT") and Urticaria Activity Score ("UAS7") were collected over a 4-week screening period. Patients with baseline UCT scores of less than 12, indicative of poorly controlled urticaria, were enrolled in the study and treated with up to 6 doses of lirentelimab given once monthly. Patients received an initial dose of 0.3 mg/kg at baseline, followed by a dose of 1.0 mg/kg on day 28, and then received monthly doses of either 1.0 or 3.0 mg/kg for a total of 6 doses. The primary endpoint of the trial was patient-reported symptoms measured by the UCT. Secondary endpoints include safety and tolerability, as well as patient-reported symptoms as measured by UAS7 (CSU patients only), pulse controlled ergometry (cholinergic urticaria patients only), and Fric testing (symptomatic dermographism patients only).

Results for each cohort are shown in Figure 9. Patients in all cohorts reported high levels of disease control and some patients experienced complete resolution of symptoms while receiving lirentelimab. Importantly, lirentelimab also produced high levels of response in patients that were refractory to Xolair. This suggests that lirentelimab, if approved, could become the treatment of choice for antihistamine refractory CU patients. Additionally, lirentelimab depleted blood eosinophils in subjects throughout the dosing period.

Figure 9. Data from the Phase 2 CU clinical trial

Xolair Naïve CSU Cohort (N=13)	Baseline	Week 22
Average UCT Score	3.2	14.2
UCT Complete Response	—	12/13 (92%)
UCT Partial Response	—	0/13 (0%)
UCT No Response	—	1/13 (8%)
Average UAS7 Score	18.5	4.6 (-75%)
Proportion with UAS7 ≤ 6	0%	8/13 (62%)
Proportion with UAS7 = 0	0%	7/13 (54%)
Proportion with ISS7 = 0	0%	7/13 (54%)
Proportion with HSS7 = 0	0%	10/13 (77%)

Xolair Failure CSU Cohort (N=11)	Baseline	Week 22
Average UCT Score	3.7	8.5
UCT Complete Response	—	4/11 (36%)
UCT Partial Response	—	2/11 (18%)
UCT No Response	—	5/11 (45%)
Average UAS7	28.7	14.7 (-49%)
Proportion with UAS7 ≤ 6	0%	2/11 (18%)
Proportion with UAS7 = 0	0%	1/11 (9%)
Proportion with ISS7 = 0	0%	1/11 (9%)
Proportion with HSS7 = 0	0%	1/11 (9%)

Cholinergic Urticaria Cohort (N=11)	Baseline	Week 22
Average UCT Score	5.4	11.8
UCT Complete Response	—	9/11 (82%)
UCT Partial Response	—	0/11 (0%)
UCT No Response	—	2/11 (18%)
Pulse Control Ergometry Exercise Test Negative	0%	7/7 (100%)

Symptomatic Dermographism Cohort (N=10)	Baseline	Week 22
Average UCT Score	5.7	9.1
UCT Complete Response	—	4/10 (40%)
UCT Partial Response	—	3/10 (30%)
UCT No Response	—	3/10 (30%)
Fric Test Itch Negative	0%	5/10 (50%)
Fric Test Hives Negative (Critical Friction Threshold)	0%	4/10 (40%)

Intravenous lirentelimab was generally well tolerated in the Phase 2 CU study. The most common adverse event was the occurrence of mild to moderate IRRs such as flushing, feeling of warmth, headache, nausea or dizziness, which occurred in 34% of first infusions and 4% of subsequent infusions.

Severe Allergic Conjunctivitis

Disease Overview

Atopic keratoconjunctivitis (“AKC”), vernal keratoconjunctivitis (“VKC”) and perennial allergic conjunctivitis (“PAC”) are a set of allergic ocular conjunctival diseases primarily associated with an IgE-mediated hypersensitivity reaction. We are focused on SAC, the severe forms of these collective diseases. These conditions are often caused by airborne allergens, such as grass and tree pollens, coming into contact with the eyes, which induces IgE mediated mast cell degranulation and allergic inflammation. The inflammatory mediators released by the mast cell result in inflammation and the infiltration of eosinophils, neutrophils and other immune cells. Eosinophils and mast cells are believed to be the main effector cells, with protease secretions directly damaging the

conjunctiva, and play a key role in triggering and maintaining the inflammatory response. Symptoms include itching, hyperemia, light sensitivity (or "photophobia"), pain, eye discharge and the sensation of having a foreign body in the eye. These symptoms can affect quality of life and daily activities, such as reading, driving and being in bright outdoor environments. In addition, patients with untreated disease, in particular those with VKC and AKC, can experience remodeling of the ocular surface tissues that can lead to vision loss. In addition to the primary symptoms of allergic conjunctivitis, a high correlation of allergic rhinitis, allergic asthma and atopic dermatitis comorbidities occur in this patient population. We believe that approximately 50,000-150,000 patients in the United States suffer from SAC and could be candidates for treatment with lirentelimab.

Current Therapies and Limitations

PAC is treated with topical antihistamines and mast cell stabilizers. More serious forms are treated with topical and systemic corticosteroids, cyclosporine and other immunomodulatory drugs. There are no drugs approved for AKC and VKC, and as a result, patients are typically treated similarly to patients with PAC. Unfortunately, many patients continue to have symptoms despite these topical and/or systemic treatments and many of the drugs are not suitable for long-term treatment due to undesirable side effects.

Study Design and Results

We conducted an open-label Phase 1 study with lirentelimab in patients with SAC. The trial was open-label, multi-dose, six-month study and enrolled 29 total SAC patients. Of the 29 patients, 13 patients had AKC, 15 patients had PAC, and one patient had VKC. Patients received a 0.3 mg/kg dose of lirentelimab for the first month, followed by a 1 mg/kg dose the next month, then monthly doses of 1 or 3 mg/kg for four additional months. The primary endpoint of the trial was safety and tolerability. Key secondary endpoints included patient-reported symptom measures of ocular itch, pain, lacrimation, photophobia and foreign body sensation. Patients administered lirentelimab reported a 78% median improvement in ocular symptoms by ACS and a 71% median improvement in physician assessed signs and symptoms using the OSS. In addition, a number of patients enrolled in the trial also had concomitant allergic rhinitis, asthma, and atopic dermatitis. Patients suffering from comorbid atopic dermatitis, asthma and allergic rhinitis, despite treatment with currently available therapies, reported improvements in their symptoms while receiving lirentelimab.

Intravenous lirentelimab was generally well tolerated. The most common adverse event was mild to moderate IRRs, such as flushing, feeling of warmth, headache, nausea, dizziness, which occurred mostly during the first infusion.

Figure 10. SAC Phase 1 Trial Results

ACS Symptom (N=29)	**Patient Assessed Median Change from Baseline to Weeks 21 to 22**
Itching	-75%
Light Sensitivity	-57%
Eye Pain	-75%
Foreign Body Sensation	-80%
Watering Eyes	-76%

OSS Symptom (N=29)	**Investigator Assessed Median Change from Baseline to Day 140**
Itching	-67%
Redness	-67%
Tearing	-50%
Chemosis	-100%

Comorbid Condition	Patient Assessed Change in Median Global Severity from Baseline to Weeks 21 to 22
Asthma (N = 9)	-72%
Atopic Dermatitis (N = 11)	-65%
Rhinitis (N = 11)	-69%

Indolent Systemic Mastocytosis

Disease Overview

ISM is a rare disease characterized by the clonal proliferation and accumulation of mast cells in the bone marrow, respiratory and gastrointestinal tracts, and organs such as the skin, liver, spleen and brain. Common symptoms include pruritus, flushing, headache, cognitive impairment, fatigue, diarrhea, gastrointestinal cramps, hypotension and skin lesions, as well as an increased risk for osteoporosis and anaphylaxis, which in some cases can be life threatening. The symptoms of ISM are attributed to mast cell activation and the systemic release of mediators. Approximately 30,000 patients in the United States suffer from ISM. Lirentelimab has received orphan drug designation from the FDA and the European Medicines Agency ("EMA") for the treatment of ISM.

Current Therapies and Limitations

There are currently no drugs approved for the treatment of ISM by the FDA or EMA. ISM is treated with drugs targeting mast cell mediators, including antihistamines, cromolyn sodium and leukotriene blocking agents. Most patients' symptoms remain poorly controlled by these treatments. Glucocorticoids can provide temporary relief in some cases; however long-term treatment with steroids is not appropriate due to their many side effects.

Study Design and Results

Lirentelimab has been evaluated in an open-label, single and multiple ascending dose Phase 1 study in patients with ISM. The single dose portion of this trial was completed during the second quarter of 2017, with subsequent completion of the six-month multi-dose portion in the first quarter of 2019. The primary endpoints of the trial were safety and tolerability. Key secondary endpoints were the pharmacokinetic and pharmacodynamic profile of lirentelimab, including peripheral counts of eosinophils and patient-reported mastocytosis disease symptoms including itching, hives, skin flushing, diarrhea, abdominal pain, fatigue, headache, difficulty concentrating and muscle and joint pain. In the single dose portion, 13 patients received single escalating doses of 0.0003 to 1.0 mg/kg, including three patients receiving 0.3 mg/kg and three patients receiving 1.0 mg/kg of lirentelimab. Five out of six patients receiving 0.3 or 1.0 mg/kg reported to the study investigators that they had improvements in symptoms, including diarrhea, abdominal pain, fatigue, pruritus, difficulty concentrating and headaches.

In the multi-dose portion of the trial, 6 patients received six doses of 1.0 mg/kg of lirentelimab given monthly and 5 patients received 1.0 mg/kg for the first month and then monthly doses of 3.0 to 10 mg/kg of lirentelimab for the five months thereafter. Depletion of eosinophils was observed for all patients throughout the dosing period with lirentelimab. ISM symptoms and quality of life were assessed using the Mastocytosis Questionnaire ("MSQ"), an internally developed Patient Reported Outcome ("PRO") instrument, the Mastocytosis Questionnaire ("MSQ"), as well as two published questionnaires, the Mastocytosis Activity and Symptom Severity questionnaire ("MAS") and the Mastocytosis Quality of Life questionnaire ("MC-QoL"). The MSQ is a proprietary daily PRO Mastocytosis Questionnaire that we developed based on published guidance from the FDA on the development of PRO instruments and is expected to be used to help determine safety and efficacy in future clinical trials. The MSQ consists of nine symptom assessments, with each symptom being scored on a 0-10 scale with higher values representing greater symptom burden. Total score for the MSQ ranges from 0-90 points. For each PRO, baseline scores were collected over 14 to 28 days and compared to scores at Weeks 21 to 22, two weeks after the final dose of lirentelimab. PRO data obtained from patients in the multidose portion of the trial are presented in Figure 11. Consistent with the improvements reported in the single ascending dose study, lirentelimab produced clinically meaningful improvement in patient symptoms for multiple symptoms across all three PROs used in the study.

Figure 11. Patient Reported Outcomes from multi-dose portion of ISM trial

MSQ Symptom (N=8) [1]	Median Change from Baseline at Weeks 21 to 22
Itching	-56%
Hives	-38%
Flushing (#)	-46%
Abdominal Pain	-60%
Diarrhea	-49%
Headache	-50%
Fatigue	-47%
Difficulty Concentrating	-59%
Muscle Pain	-27%
Joint Pain	-26%

1 The MSQ was not available for use in 3 patients.

MAS2 Symptom (N=11)	Median Change from Baseline at Weeks 21 to 22
Itching	-53%
Hives	-59%
Flushing	-57%
Abdominal Pain	-84%
Diarrhea	-72%
Headache	-57%
Fatigue	-22%
Difficulty Concentrating	-30%
Bone-Joint-Muscle Pain	-22%

MC-QoL Domain (N=11)	Median Change from Baseline at Day 145
Symptoms	-39%
Social Life / Functioning	-42%
Emotions	-57%
Skin	-44%

Intravenous lirentelimab was generally well tolerated in the Phase 1 ISM study. The most common adverse event was the occurrence of mild to moderate IRRs, such as flushing, feeling of warmth, headache, nausea or dizziness, which occurred mostly during the first infusion.

Preclinical Results

Lirentelimab Results in Animal Disease Models Suggest Broad Activity

Because Siglec-8 is found only in cells of humans and certain other primates, we have developed a proprietary Siglec-8 transgenic mouse, in which Siglec-8 is expressed with a similar tissue distribution to humans and is functionally active. The transgenic mouse provides us with a proprietary tool to assess the safety, tolerability and activity of anti-Siglec-8 antibodies.

Lirentelimab has completed short- and long-term toxicity studies in Siglec-8 transgenic mice. Chronic weekly dosing for six months with lirentelimab in transgenic mice at dose levels of 50 or 100 mg/kg resulted in no adverse drug-related findings in mortality, clinical observations, body weight, food consumption and anatomic pathology after the end of dosing. Non-adverse findings included decreases in eosinophil counts in both sexes at 50 mg/kg/week, which persisted through the recovery period. These findings reflect the expected pharmacology of

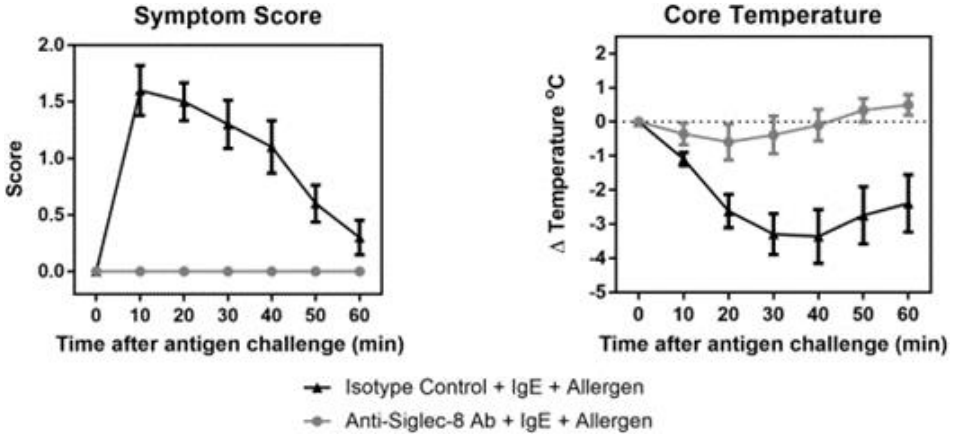
lirentelimab. The no-observed-adverse-effect-level of lirentelimab after chronic dosing for six months was 100 mg/kg/week.

We have shown that lirentelimab or antibodies to Siglec-8 have broad activity in animal disease models (eosinophilic gastroenteritis, anaphylaxis, fibrosis, chronic obstructive pulmonary disease, and Substance P mediated inflammation) and in human *ex vivo* diseased tissue (eosinophilic gastrointestinal disease, mastocytosis, atopic dermatitis and lung).

Anti-Siglec-8 Antibody Inhibits IgE Mediated Systemic Anaphylaxis in Mouse Model

The ability of an anti-Siglec-8 antibody to inhibit IgE-mediated mast cell activation was demonstrated in a mouse model of systemic anaphylaxis. Anaphylaxis occurs due to IgE-mediated release of inflammatory mediators and cytokines from mast cells, which results in vasodilation, a reduction in core body temperature, itchiness and bronchoconstriction, among other symptoms. In this model, “humanized” mice engrafted with human immune cells were pretreated with an anti-Siglec-8 antibody or an isotype control antibody, administered an allergen-specific IgE, and 24 hours later, anaphylaxis was triggered using an allergen. Mice treated with the isotype control antibody plus IgE and allergen displayed symptoms of anaphylaxis and body temperature decreases that peaked 10 to 40 minutes after inducing anaphylaxis. In contrast, mice treated with the anti-Siglec-8 antibody plus IgE and allergen displayed no observable symptoms and had no significant changes in core body temperature.

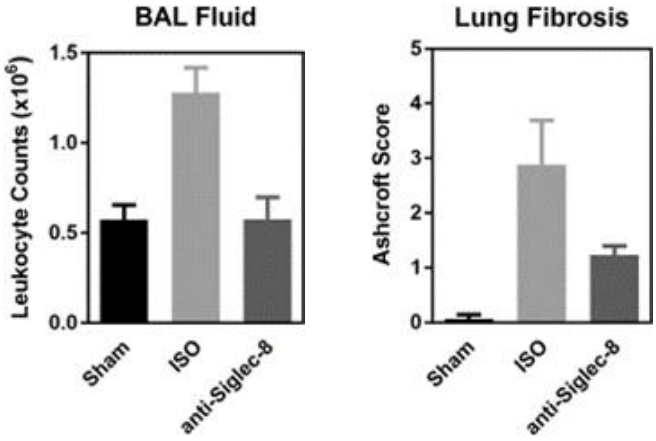
Figure 12. Effects of Anti-Siglec-8 in a Mouse Model of Systemic Anaphylaxis



Anti-Siglec-8 Antibody Decreases Bleomycin Induced Lung Fibrosis in Mouse Model

Lung fibrosis induced by bleomycin is believed to be due to the increased expression of IL-33. IL-33 induces mast cells to release mediators that activate fibroblasts leading to fibrosis and collagen deposition. In this model, lung fibrosis was induced by administering bleomycin to Siglec-8 transgenic mice every other day for 30 days. On days 14, 21 and 28, an anti-Siglec-8 or isotype control antibody was administered. Fibrosis was assessed on day 30 for anti-Siglec-8 or isotype control antibody treated mice and compared to sham treated mice (mice that did not receive bleomycin). Relative to control antibody mice, mice treated with an anti-Siglec-8 antibody displayed minimal fibrotic changes. In addition, the bronchoalveolar lavage ("BAL") of anti-Siglec-8 treated mice displayed reduced levels of infiltrating leukocytes that were similar to sham treated animals.

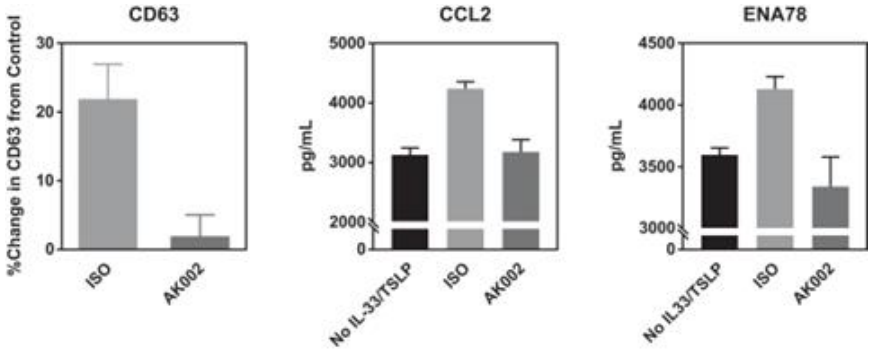
Figure 13. Leukocyte Counts and Lung Fibrosis in Bleomycin Lung Fibrosis Model



Anti-Siglec-8 Antibody Inhibits IL-33/TSLP Activation of Mast Cells from Human Skin

IL-33 combined with TSLP is a potent activator of mast cells and results in increased expression of the mast cell activation marker CD63. Mast cells isolated from skin showed a 20% increase in the expression of CD63 after overnight exposure to IL-33 and TSLP. In contrast, skin mast cells treated with lirentelimab along with IL-33 and TSLP did not show increased activation, with CD63 levels remaining similar to control levels (no IL-33 and TSLP exposure). In addition, the levels of chemokines CCL2 and ENA78 did not increase after stimulation with IL-33 and TSLP in the presence of lirentelimab. Chemokines are known to recruit and activate cells of the innate and adaptive immune system. By normalizing chemokine secretions, lirentelimab may be able to prevent further recruitment of immune cells and thereby interrupt the inflammatory cascade.

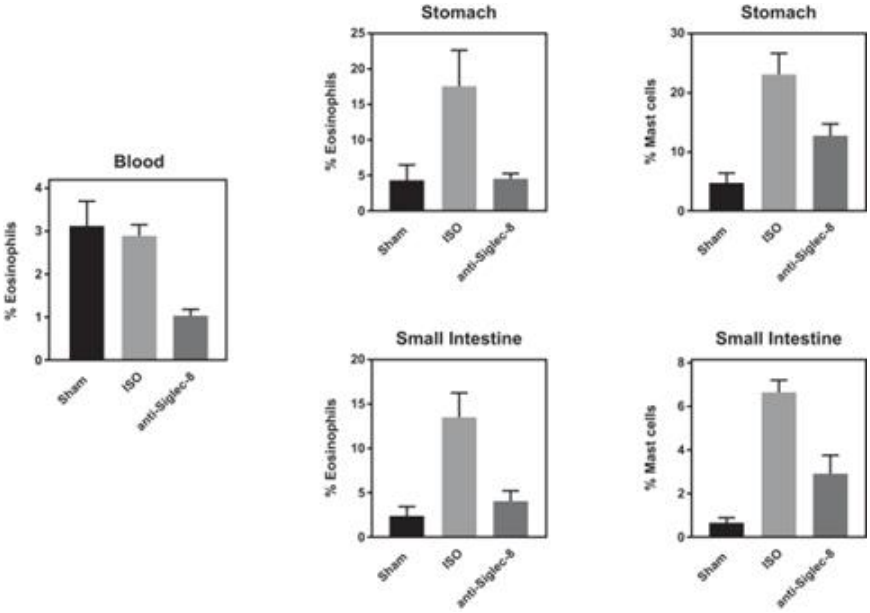
Figure 14. ***Ex Vivo*** **Skin Tissue Response to IL33/TSLP**



Anti-Siglec-8 Antibody Reduces Eosinophil and Mast Cell Levels in EG/EoD Model

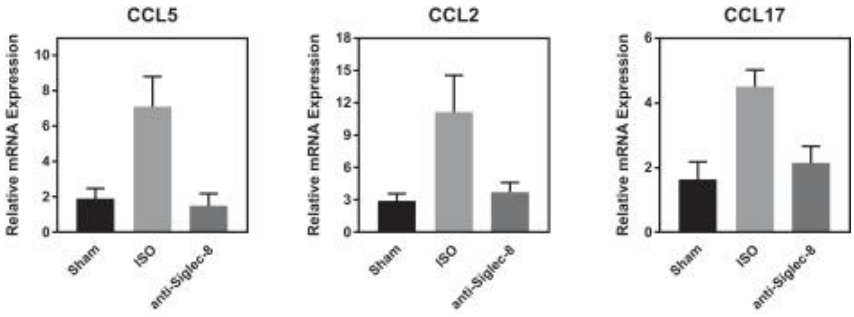
In this model, two groups of Siglec-8 transgenic mice were sensitized with ovalbumin to induce eosinophil and mast cell driven gastrointestinal inflammation similar to that observed in EG and other EGIDs. A third group of animals was administered phosphate buffered saline to serve as normal unsensitized sham controls ("sham"). Treatment with a single dose of anti-Siglec-8 antibody led to lower levels of eosinophils in the blood, stomach and small intestine and reduced numbers of mast cells in the stomach and small intestine compared to mice that received an isotype control antibody ("ISO").

Figure 15. EG/EoD Model Eosinophil and Mast Cell Counts in Blood, Stomach and Small Intestine



Anti-Siglec-8 treatment also reduced the levels of multiple important chemokines (CCL5/Rantes, CCL2/MCP-1, CCL17) to the levels of sham control animals. Chemokines are known to recruit and activate cells of the innate and adaptive immune system. By normalizing chemokine secretions, lirentelimab may be able to reduce further recruitment of immune cells and thereby interrupt the inflammatory cascade.

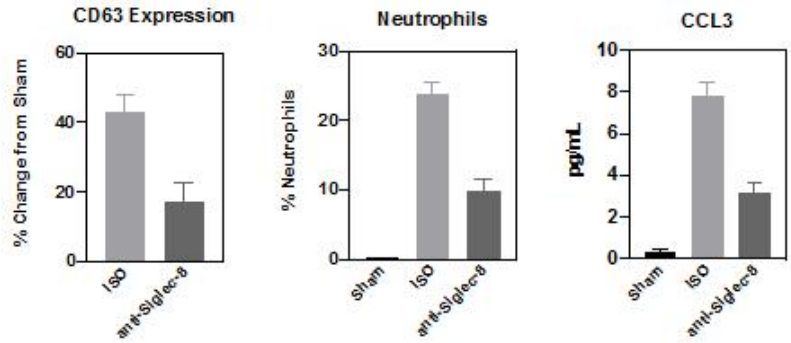
Figure 16. Chemokine Levels in the EG/EoD Mouse Model



Anti-Siglec-8 Antibody Inhibits MRGPRX2-Mediated Mast Cell Activation in Mouse Model

The mast cell specific MRGPRX2 receptor is a potent activator of mast cells and is believed to contribute chronic inflammation, itch, and pain in a number of diseases due to the presence of the MRGPRX2 ligand, Substance P. In a mouse model of Substance P mediated inflammation, Substance P was administered to Siglec-8 transgenic mice to induce mast cell activation and inflammation. An anti-Siglec-8 or isotype control antibody was administered 1 hour after Substance P. Relative to isotype control antibody mice ("ISO'), mice treated with an anti-Siglec-8 antibody displayed reduced MRGPRX2-mediated mast cell activation as assessed by CD63 expression compared to sham treated mice (mice that did not receive Substance P). In addition, anti-Siglec-8 treated mice displayed reduced levels of infiltrating neutrophils and inflammatory mediators (CCL3) compared to isotype control mice.

Figure 17: Mast Cell Activation and Inflammation in MRGPRX2 Mouse Model



In the above models, anti-Siglec-8 antibodies have significantly reduced eosinophils and inhibited mast cells. The activity in these models suggests lirentelimab has the potential to treat eosinophil and mast cell inflammation in a number of disease settings and highlights the ability of lirentelimab to inhibit the inflammatory cascade triggered by different activating signals.

Preclinical Programs

We are developing additional antibodies targeting novel immune system receptors. These antibodies have demonstrated promising in vitro and animal activity and are being evaluated for further development.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid technological advancement, significant competition and an emphasis on intellectual property. We face potential competition from many different sources, including major and specialty pharmaceutical and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with current therapies and new therapies that may become available in the future. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety profile, convenience, cost, level of promotional activity devoted to them and intellectual property protection.

We are not aware of any other company or organization that is conducting clinical trials of a product candidate that targets both mast cells and eosinophils, including any product candidate that specifically targets Siglec-8. The competition we may face with respect to each of the indications we are targeting with lirentelimab includes:

- ***EG, EoD and EoE.*** Currently, there are no therapies that have been approved by the FDA specifically for EG, EoD or EoE. Several companies, including but not limited to, Regeneron (dupilumab), AstraZeneca (benralizumab), Bristol Myers Squibb (cendakimab), Shire (oral budesonide), and Dr. Falk Pharma (oral budesonide) have or are conducting studies in these indications.
- ***ISM.*** We are not aware of any FDA-approved treatments for ISM. Blueprint Medicines is developing avapritinib in smoldering systemic mastocytosis and ISM.
- ***CU.*** Omalizumab (Roche and Novartis) is an FDA-approved drug for the treatment of CSU. We are not aware of any FDA-approved treatment options for cholinergic urticaria or symptomatic dermatographism. Companies conducting studies in chronic spontaneous urticaria include: Novartis (ligelizumab), Genentech (fenebrutinib), Regeneron (dupilumab), Celldex (CDX-0159), and Gossamer Bio (GB100).
- ***SAC.*** The products that are currently available for treatment of SAC only provide temporary relief for most patients and have little effect on moderate to severe cases. Companies conducting studies in SAC include Aldeyra (reproxalap).

Many of the companies against which we may compete have significantly 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. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Sales and Marketing

In light of our stage of development, we currently have limited marketing and sales capabilities. We hold worldwide commercialization rights to all of our product candidates. We intend to retain the rights to our compounds in key markets for the time being, and plan to build our own focused, specialty sales force to commercialize approved products in the United States.

Manufacturing

We must manufacture drug product for clinical trial use in compliance with cGMP regulations. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our product candidates must meet cGMP requirements and FDA or comparable foreign regulatory authority’s satisfaction before any product is approved and our commercial products can be manufactured. Our third-party manufacturers will also be subject to periodic inspections of facilities by the FDA and other foreign authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

We do not currently have the infrastructure or internal capability to manufacture our product candidates for use in clinical development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates in compliance with cGMP requirements clinical trials under our guidance. In the case of lirentelimab, we rely on a single third-party manufacturer, Lonza, and we currently have no alternative manufacturer in place. We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We have personnel with significant technical, manufacturing, analytical, quality, regulatory, cGMP and project management experience to oversee our third-party manufacturers and to manage manufacturing and quality data and information for regulatory compliance purposes.

Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. Any of these actions or events could have a material impact on the availability of our products.

In-Licensing Agreements

We have entered into two in-licensing agreements with third-parties for the development, manufacturing and commercialization of our products including lirentelimab. The specific terms of the individual agreements are discussed in further detail below.

Exclusive License Agreement with The Johns Hopkins University

We have exclusively licensed intellectual property from The Johns Hopkins University ("JHU") in a license agreement dated December 20, 2013 and amended and restated September 30, 2016. In December 2013, we entered into an agreement with JHU for an exclusive worldwide license to develop and commercialize for the treatment and prevention of disease products covered by the JHU licensed patent rights or derived from materials provided by JHU. In September 2016, we and JHU amended and restated the license agreement to an exclusive worldwide license to develop and commercialize in all fields products covered by the licensed patent rights, or derived from materials provided by JHU.

Under the license agreement we are obligated to make payments to JHU for therapeutic products aggregating up to $4.0 million based on achieving specified development and regulatory approval milestones. We will also pay single-digit royalties to JHU based on net sales of each licensed therapeutic product by us and our affiliates and sublicensees and have up to a low six-digit dollar minimum annual royalty payment. In addition, in the event we sublicense the JHU intellectual property, we are obligated to pay JHU a specified portion of income we receive from sublicensing.

Our royalty obligation with respect to each licensed product in a country extends until the later of the expiration of the last-to-expire patent licensed from JHU covering the licensed product in the country or the expiration of a specified number of years after the first commercial sale of any licensed product in any country. The latest possible expiration date of patents licensed under the agreement is 2021 in all applicable countries, in the absence of any patent extensions that may be available for such patents.

Non-Exclusive License Agreement with BioWa Inc. and Lonza Sales AG

We have licensed on a non-exclusive basis intellectual property from BioWa Inc. ("BioWa") and Lonza pursuant to a license agreement dated October 31, 2013. The agreement grants Allakos a non-exclusive worldwide license to develop and commercialize certain products manufactured in a particular mammalian host cell line for the prevention, diagnosis or treatment of human disease.

Under the license agreement, we are obligated to pay BioWa an annual commercial license fee of $40,000 until such time as BioWa receives royalty payments. We may also become obligated to make payments to BioWa aggregating up to $41.0 million based on achieving specified milestones, and to pay low single-digit royalties to

BioWa based on net sales of licensed product by us and our affiliates and sublicensees. Our royalty obligation to BioWa with respect to each licensed product in a country extends until the later of the expiration of the last-to-expire licensed patent covering the licensed product in the country or the expiration of either regulatory exclusivity or a specified number of years after the first commercial sale of the licensed product in the country, whichever is later.

We may also pay low single-digit royalties to Lonza based on net sales of each licensed product by us and our affiliates and sublicensees. We will be required to pay an annual license fees to Lonza if we (or our strategic partner) manufactures a particular product using the particular cell line, or if we utilize a third party CMO to manufacture a product using such system. Our royalty obligation to Lonza with respect to each licensed product in a country extends until the later of the expiration of the last-to-expire licensed patent covering the licensed product in the country or a specified number of years after the first commercial sale of the licensed product in the country, whichever is later. The latest possible expiration date of patents licensed under the agreement is 2021 or 2023, depending on the country, in the absence of any patent extensions that may be available for such patents.

Total Royalty Burden

In aggregate, we anticipate our total royalty obligation on lirentelimab from our in-licensing agreements will be a mid-single digit percentage of net sales by us and our affiliates and sublicensees.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug Development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations, and biologics under the FDCA, the Public Health Service Act (“PHSA”) and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Any future product candidates must be approved by the FDA through either a BLA or New Drug Application (“NDA”) process before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice (“GLP”), requirements;
- submission to the FDA of an Investigational New Drug (“IND”) application, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board (“IRB”), or ethics committee at each clinical trial site before each trial may be initiated;

- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice ("GCP"), requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA or BLA;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to accept the filing for review;
- satisfactory completion of a FDA pre-approval inspection of the manufacturing facility or facilities where the drug or biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug or biologic's identity, strength, quality and purity;
- potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA or BLA;
- FDA review and approval of the NDA or BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug or biologic in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS"), and the potential requirement to conduct post-approval studies.

The data required to support an NDA or BLA are generated in two distinct developmental stages: preclinical and clinical. The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for any future product candidates will be granted on a timely basis, or at all.

Preclinical Studies and IND

The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the 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.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue 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 one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy.

Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials in the United States generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability and safety of the drug.
- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug or biologic, findings from animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or 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 check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as 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, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that our product candidates do not undergo unacceptable deterioration over their shelf life.

NDA/BLA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA or BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. In short, the NDA or BLA is a request for approval to market the drug or biologic for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity and potency for a biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA or BLA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through December 31, 2021, the user fee for an application requiring clinical data, such as an NDA or BLA, is $2.9 million. PDUFA also imposes an annual program fee for human drugs and biologics of $0.3 million. 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 NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs and BLAs before it accepts them for filing, and may request additional information rather than accepting the NDA or BLA for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months, from the filing date, in which to complete its initial review of a new molecular-entity NDA or original BLA and respond to the applicant, and six months from the filing date of a new molecular-entity NDA or original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving an NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. 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 within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which 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, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug 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 usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA,

addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in 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 drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if a product candidate is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for fast track designation if they are intended to treat a serious or life threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA or BLA approval, but ideally no later than the pre-NDA or pre-BLA meeting.

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. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM"), which is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions, as it deems necessary to assure safe use of the product.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, 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. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

Abbreviated Licensure Pathway of Biological Products as Biosimilar or Interchangeable

The Patient Protection and Affordable Care Act, or Affordable Care Act ("ACA"), signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), created an abbreviated approval pathway for biological products shown to be highly similar to an FDA-licensed reference biological product. The BPCIA attempts to minimize duplicative testing, and thereby lower development costs and increase patient access to affordable treatments. An application for licensure of a biosimilar product must include information demonstrating biosimilarity based upon the following, unless the FDA determines otherwise:

- analytical studies demonstrating that the proposed biosimilar product is highly similar to the approved product notwithstanding minor differences in clinically inactive components;
- animal studies (including the assessment of toxicity); and
- a clinical trial or trials (including the assessment of immunogenicity and PK or PD) sufficient to demonstrate safety, purity and potency in one or more conditions for which the reference product is licensed and intended to be used.

In addition, an application must include information demonstrating that:

- the proposed biosimilar product and reference product utilize the same mechanism of action for the condition(s) of use prescribed, recommended or suggested in the proposed labeling, but only to the extent the mechanism(s) of action are known for the reference product;
- the condition or conditions of use prescribed, recommended or suggested in the labeling for the proposed biosimilar product have been previously approved for the reference product;
- the route of administration, the dosage form and the strength of the proposed biosimilar product are the same as those for the reference product; and
- the facility in which the biological product is manufactured, processed, packed or held meets standards designed to assure that the biological product continues to be safe, pure and potent.

Biosimilarity means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. In addition, the law provides for a designation of "interchangeability" between the reference and biosimilar products, whereby the biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. The higher standard of interchangeability must be demonstrated by information sufficient to show that:

- the proposed product is biosimilar to the reference product;
- the proposed product is expected to produce the same clinical result as the reference product in any given patient; and
- for a product that is administered more than once to an individual, the risk to the patient in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the reference product is no greater than the risk of using the reference product without such alternation or switch.

FDA approval is required before a biosimilar may be marketed in the United States. However, complexities associated with the large and intricate structures of biological products and the process by which such products are manufactured pose significant hurdles to the FDA's implementation of the law that are still being worked out by the

FDA. For example, the FDA has discretion over the kind and amount of scientific evidence—laboratory, preclinical and/or clinical—required to demonstrate biosimilarity to a licensed biological product.

The FDA intends to consider the totality of the evidence, provided by a sponsor to support a demonstration of biosimilarity, and recommends that sponsors use a stepwise approach in the development of their biosimilar products. Biosimilar product applications thus may not be required to duplicate the entirety of preclinical and clinical testing used to establish the underlying safety and effectiveness of the reference product. However, the FDA may refuse to approve a biosimilar application if there is insufficient information to show that the active ingredients are the same or to demonstrate that any impurities or differences in active ingredients do not affect the safety, purity or potency of the biosimilar product. In addition, as with BLAs, biosimilar product applications will not be approved unless the product is manufactured in facilities designed to assure and preserve the biological product's safety, purity and potency.

The submission of a biosimilar application does not guarantee that the FDA will accept the application for filing and review, as the FDA may refuse to accept applications that it finds are insufficiently complete. The FDA will treat a biosimilar application or supplement as incomplete if, among other reasons, any applicable user fees assessed under the Biosimilar User Fee Act of 2012 have not been paid. In addition, the FDA may accept an application for filing but deny approval on the basis that the sponsor has not demonstrated biosimilarity, in which case the sponsor may choose to conduct further analytical, preclinical or clinical studies and submit a BLA for licensure as a new biological product.

The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the branded product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving any products that are biosimilar to the branded product. The FDA cannot approve a biosimilar application for twelve years from the date of first licensure of the reference product. Additionally, a biosimilar product sponsor may not submit an application for four years from the date of first licensure of the reference product. A reference product may also be entitled to exclusivity under other statutory provisions. For example, a reference product designated for a rare disease or condition (an "orphan drug") may be entitled to seven years of exclusivity, in which case no product that is biosimilar to the reference product may be approved until either the end of the twelve-year period provided under the biosimilarity statute or the end of the seven-year orphan drug exclusivity period, whichever occurs later. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block biosimilarity applications from being approved on or after the patent expiration date. In addition, the FDA may under certain circumstances extend the exclusivity period for the reference product by an additional six months if the FDA requests, and the manufacturer undertakes, studies on the effect of its product in children, a so-called pediatric extension.

The first biological product determined to be interchangeable with a branded product for any condition of use is also entitled to a period of exclusivity, during which time the FDA may not determine that another product is interchangeable with the reference product for any condition of use. This exclusivity period extends until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit against the applicant that submitted the application for the first interchangeable product is still ongoing or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued.

Post-Approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, requirements to report adverse experiences and comply with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug or

biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a REMS, to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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

Other U.S. Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

For example, in the United States, sales, marketing and scientific and educational programs also must comply with state and federal fraud and abuse laws. These laws include the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. Moreover, the ACA provides that the government may assert 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 False Claims Act.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of biologic and pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

U.S. Patent-Term Restoration and Marketing Exclusivity

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

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of a NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA"), or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for a NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

A reference biological product is granted twelve years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

European Union Drug Development

As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority (“NCA”), and one or more Ethics Committees (“ECs”). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical. In the meantime, Clinical Trials Directive 2001/20/EC continues to govern all clinical trials performed in the EU.

European Union Drug Review and Approval

In the European Economic Area (“EEA”), which is comprised of the 27 Member States of the European Union (including Norway and excluding Croatia), Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization (“MA”). There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (“CHMP”), of the EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time

of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State ("RMS"). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics ("SPC"), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Coverage and Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price ("AMP"), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. The Centers for Medicare & Medicaid Services ("CMS"), have proposed to expand Medicaid rebate liability to the territories of the United States as well.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be

developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug prices are determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Human Capital

We believe we must attract, develop, motivate and retain exceptional employees to achieve our objectives. To accomplish this, we offer competitive compensation, promote diversity and inclusion, and focus on employee health, safety and well-being. Our board of directors engages regularly with management on human capital matters. As of December 31, 2020, we had 125 full-time employees, 87 of whom were engaged in research and development activities. None of our employees are represented by a labor union or covered under a collective bargaining agreement, and we consider our relationship with our employees to be good.

Facilities

Our corporate headquarters are currently located in Redwood City, California, where we lease 25,136 square feet of office, research and development and laboratory space pursuant to a lease agreement that expires on July 31, 2029. The lease agreement includes an option to extend the term for an additional period of five years, and provides us a right of first offer to expand into available space on the first floor of the building. We are responsible for payment of our proportionate share of taxes and operating expenses for the building, in addition to monthly base rent in the initial amount of $0.1 million, with 3% annual increases, which monthly base rent is abated for the first nine months of the lease term. We provided a security deposit under the lease in the form of a letter of credit in the initial amount of $0.8 million, subject to a reduction to $0.4 million following the 45th month of the term and the satisfaction of certain conditions. On December 4, 2019, we entered into a lease agreement for approximately

98,000 square feet of office space to be constructed in San Carlos, California. These premises were delivered in November 2020, and we expect to move into this new headquarters in second half of 2021 after making certain improvements. The lease term will expire 123 months following the rent commencement date, which is expected to be the earlier of nine months after the premises are delivered or the date our tenant improvements are substantially completed. Upon commencement of the lease term, we will be responsible for monthly base rent payments of $5.75 per rentable square foot. We provided a security deposit in the form of a letter of credit in the amount of $1.5 million. This lease agreement includes an option to extend the term for an additional period of five years and provides us a right of first refusal for certain additional office space. We believe that these facilities will be adequate for our near-term needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

Legal Proceedings

For information on our legal proceedings, see Item 3, *Legal Proceedings*, in this Annual Report on Form 10-K.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. Our patent portfolio is intended to cover our product candidates and components thereof, their methods of use and processes for their manufacture, our proprietary reagents and assays and any other inventions that are commercially important to our business. We also rely on trade secret protection of our confidential information and know-how relating to our proprietary technology, platforms and product candidates.

We believe that we have substantial know-how and trade secrets relating to our technology and product candidates. Our patent portfolio as of February 23, 2021 contains eight issued and unexpired U.S. patents and seven pending U.S. utility patent applications that are solely owned or exclusively licensed by us and numerous foreign counterparts of these patents and patent applications.

We have exclusively licensed from JHU four issued and unexpired U.S. patents and also foreign counterparts, with claims granted in Europe and Japan. The JHU licensed patent rights include issued U.S. patents with claims that recite anti-Siglec-8 antibodies comprising the CDRs of a particular antibody and methods of use a class of antibodies that bind to Siglec-8 for treating particular diseases. We own four granted U.S. patents that claim the active component of lirentelimab, an anti-Siglec-8 antibody, pharmaceutical compositions comprising lirentelimab, and methods for the treatment of particular diseases using antibodies to Siglec-8, with a projected expiration date in 2035 in the absence of patent extensions. Similar patents are issued in Europe, Japan and other territories. We have twelve further pending families of patent applications that include U.S. and foreign applications relating to methods of treatment for treating particular diseases using antibodies to Siglec-8, methods of delivering antibodies to Siglec-8, and formulations for antibodies to Siglec-8. We have also filed patent applications with claims pending relating to antibodies in preclinical development and methods for treating cancer with these antibodies. We also have a non-exclusive license to intellectual property from BioWa and Lonza regarding the expression and manufacturing of monoclonal antibodies in particular mammalian host cell lines.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent’s term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under

regulatory review while the patent is in force. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended.

Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates, including lirentelimab, receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each drug and other factors. Expiration dates referred to above are without regard to potential patent term extension or other market exclusivity that may be available to us.

We also rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Corporate Information

We were incorporated in Delaware in March 2012. Our website is www.allakos.com. We use our website as a channel of distribution for company information, and financial and other material information regarding our company is routinely posted and accessible on our website.

On the Investor Relations section of our website, we post or will post, as applicable, the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission (the "SEC"): our Annual Report on Form 10-K (the "Annual Report"), our Proxy Statement on Schedule 14A, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended.

All of the information on our Investor Relations web page is available to be viewed free of charge. Information contained on our website is not part of this Annual Report or our other filings with the SEC. We assume no obligation to update or revise any forward-looking statements in this Annual Report whether as a result of new information, future events or otherwise, unless we are required to do so by law.

The SEC also maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

Impact of COVID-19 on Our Business

The pandemic caused by an outbreak of a novel coronavirus causing a disease known as COVID-19 ("COVID-19") has resulted, and is likely to continue to result, in significant national and global economic disruption and may have an adverse impact on our operations, supply chains and distribution systems or those of our contractors, and increase our expenses, including as a result of impacts associated with preventive and precautionary measures that are being taken, such as restrictions on travel, quarantine polices and social distancing. For example, the ability of our employees or those of our contractors to work has been and is likely to continue to be adversely affected. Moreover, we and our contractors have and are likely to continue to experience disruptions in supply of items that are essential for our research and development activities, including, for example, raw materials and other consumables used in the manufacturing of our product candidates or medical and laboratory supplies used in our clinical trials or preclinical studies, in each case, for which there are or may be shortages because of ongoing efforts to address the outbreak. In particular, pursuant to the U.S. Defense Production Act, as amended (the "Defense Production Act"), the U.S. federal government can require domestic industries to provide essential goods and services needed for the national defense, and they have begun to use it in the context of COVID-19 to divert supplies and materials to vaccine producers, and this has and likely will continue to cause delays with some of our suppliers.

In addition, enrollment for our clinical studies may be adversely affected and the completion of such studies may be delayed. Also, the spread of COVID-19 has disrupted the United States' healthcare and healthcare regulatory systems which could divert healthcare resources away from, or materially delay, FDA approval or any applicable foreign regulatory approval with respect to our product candidates. Furthermore, our clinical trials may be negatively affected by the COVID-19 outbreak. Given the daily evolution of the COVID-19 outbreak and the response to curb its spread, currently we are not able to estimate the effects of the COVID-19 outbreak to our results of operations or financial condition. For additional information, see "Risk Factors–*Risks Related to the Discovery, Development and Commercialization of Our Product Candidates–Our business may be adversely affected by health epidemics, including the recent coronavirus outbreak*."

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. The following discussion of risk factors contains forward-looking statements. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could materially harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business, financial condition, results of operations and growth prospects.

Risk Factors Summary

Risks Related to Our Financial Position and Need for Additional Capital

- We are engaged in clinical drug development and have a limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

- Our business may be adversely affected by health epidemics, including the recent coronavirus outbreak.
- We are dependent on the success of our lead compound, lirentelimab, which is currently in multiple clinical trials, and if we are unable to obtain approval for and commercialize lirentelimab for one or more indications in a timely manner, our business could be materially harmed.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

- The regulatory approval processes of the FDA, European Medicines Agency ("EMA") and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- We may be unable to obtain U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates.
- Our clinical trials may reveal significant adverse events, toxicities or other side effects and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

- Our success is highly dependent on the services of our Chief Executive Officer, Dr. Robert Alexander, and our President, Chief Operating Officer and Chief Financial Officer, Dr. Adam Tomasi, and our ability to attract and retain highly skilled executive officers and employees.
- If we are unable to establish sales or marketing capabilities or enter into agreements with third-parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

- 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.

Risks Related to Intellectual Property

- If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.
- We may not be able to protect our intellectual property rights throughout the world.
- Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Risks Related to Our Dependence on Third-Parties

- We rely on third-parties to conduct our clinical trials and those third-parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.
- We contract with third-parties for the production of our product candidates for preclinical studies and, in the case of lirentelimab, our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization, and this reliance on third-parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- We may not gain the efficiencies we expect from further scale-up of manufacturing of lirentelimab, and our third-party manufacturers may be unable to successfully scale-up manufacturing in sufficient quality and quantity for lirentelimab or our other product candidates, which could delay or prevent the conducting of our clinical trials or the development or commercialization of our other product candidates.

Risks Related to Ownership of Our Common Stock

- The market price of our stock may continue to be volatile, which could result in substantial losses for investors.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.
- The other factors discussed under “Risk Factors”.

General Business Risks

- If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.
- Our business activities may be subject to the Foreign Corrupt Practices Act (“FCPA”), the UK Bribery Act 2010 (“UK Bribery Act”), and other similar anti-bribery and anti-corruption laws of other countries in which we operate.
- We may experience disruptions and delays or incur financial damages as a result of system failures or security breaches.

Risks Related to Our Financial Position and Need for Additional Capital

We are engaged in clinical drug development and have a limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a clinical stage biopharmaceutical company with a limited operating history. We were incorporated and commenced operations in 2012, have no products approved for commercial sale and have not generated any

revenue. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, identifying and developing potential product candidates, conducting preclinical and clinical studies of our product candidates, including Phase 1 and Phase 2 clinical trials of lirentelimab, our lead compound. All of our product candidates currently under development, other than lirentelimab, are in preclinical development. We have not yet demonstrated our ability to successfully complete any pivotal clinical trials, obtain marketing approvals, complete large-scale drug manufacturing or arrange for a third-party to do so on our behalf or conduct sales and marketing activities. As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred net losses in each reporting period since our inception, have not generated any revenue to date and have financed our operations principally through the sale and issuance of common stock and preferred stock. Our net losses were $153.5 million, $85.4 million and $43.5 million for the year ended December 31, 2020, 2019 and 2018. As of December 31, 2020, we had an accumulated deficit of $343.0 million. We have devoted substantially all of our resources and efforts to research and development. Our lead compound, lirentelimab, is in clinical development, and our other product candidates are in preclinical development. As a result, we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter-to-quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.

Our business depends entirely on the successful development and commercialization of our product candidates. We currently generate no revenues from sales of any products. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales until sometime after we have successfully completed clinical development and received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives, including:

- successful and timely completion of preclinical and clinical development of our lead compound, lirentelimab, and any other future product candidates;
- timely receipt of marketing approvals for lirentelimab and any future product candidates for which we successfully complete clinical development and clinical trials from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;

- developing an efficient and scalable manufacturing process for lirentelimab and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third-parties to obtain finished products that are appropriately packaged for sale;
- successful launch of commercial sales following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance of lirentelimab and any future product candidates as viable treatment options by patients, the medical community and third-party payors;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio, including our licensed intellectual property;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary to develop, manufacture or commercialize our product candidates; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and/or continue our operations.

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 and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, lirentelimab and our other product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. We have also incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

As of December 31, 2020, we had $659.0 million in cash, cash equivalents and investments in marketable securities, which includes proceeds from our July 2018 initial public offering and concurrent private placement that we completed on July 23, 2018 and from our subsequent follow-on offerings in August 2019 and November 2020, after deducting underwriting discounts and commissions. We believe that our existing cash, cash equivalents and investments in marketable securities will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. Our estimate as to how long we expect our existing cash, cash equivalents and investments in marketable securities 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, cash equivalents and investments in marketable securities to fund our development of lirentelimab and for other research and development activities, working capital and other general corporate purposes. This may include additional research, hiring additional personnel, capital expenditures and the costs of operating as a public company. Advancing the development of lirentelimab and any other product candidates will require a significant amount of capital. Our existing cash, cash equivalents and investments in marketable securities will not be sufficient to fund all of the actions that are necessary to complete the development of lirentelimab or any of our other product candidates. We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

Our business may be adversely affected by health epidemics, including the recent coronavirus outbreak.

In December 2019, an outbreak of a novel coronavirus causing a disease known as COVID-19 ("COVID-19") originated and spread to a number of countries, including the U.S. On March 11, 2020, the World Health Organization characterized COVID-19 as a pandemic.

COVID-19 may have an adverse impact on our operations, supply chains and distribution systems or those of our contractors, and increase our expenses, including as a result of impacts associated with preventive and precautionary measures that are being taken, such as restrictions on travel, quarantine polices and social distancing. For example, the ability of our employees or those of our contractors to work has been and is likely to continue to be adversely affected. Moreover, we and our contractors have experienced and are likely to continue to experience disruptions in supply of items that are essential for our research and development activities, including, for example, raw materials and other consumables used in the manufacturing of our product candidates or medical and laboratory supplies used in our clinical trials or preclinical studies, in each case, for which there are or may be shortages because of ongoing efforts to address the outbreak. In particular, pursuant to the U.S. Defense Production Act, as amended (the "Defense Production Act"), the U.S. federal government may, among other things, require domestic industries to provide essential goods and services needed for the national defense, and they have begun to use the Defense Production Act in the context of COVID-19 to divert supplies and materials to vaccine producers. For example, one of our suppliers has recently informed us that, due to their obligation to prioritize other products or customers pursuant to the Defense Production Act, they are currently not able to fulfill our orders for certain materials previously ordered to be used in our manufacturing process. While this and similar delays in materials have not yet caused delays in our overall timeline for clinical trials or regulatory filings, it is quite possible that this or other such delays may occur in the future, whether as a result of actions taken pursuant to the Defense Production Act or general shortages of materials attributable to the global efforts to combat Covid-19, which could impact our proposed timeline for developing and commercializing lirentelimab and adversely impact our business, financial condition and results of operations.

In addition, the spread of COVID-19 has disrupted the United States' healthcare and healthcare regulatory systems which could divert healthcare resources away from, or materially delay, U.S. Food and Drug Administration ("FDA") approval or any applicable foreign regulatory approval with respect to our product candidates. Furthermore, our clinical trials may be negatively affected by the COVID-19 outbreak. Site initiation and patient enrollment may be delayed, for example, due to factors including prioritization of hospital resources toward the COVID-19 outbreak, travel restrictions, the inability to access sites for initiation and monitoring, and difficulties recruiting or retaining patients in our ongoing and planned clinical trials. Furthermore, if we determine that our clinical trial participants may suffer from exposure to COVID-19 as a result of their participation in our clinical studies, we may voluntarily terminate certain clinical sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. We may therefore be unable to complete our clinical trials on the timelines we expect, if at all, which could materially and adversely impact our ability to seek regulatory approval for our product candidates. COVID-19 may also reduce the effectiveness of our future sales efforts and/or impact our ability to launch and commercialize such product candidates; we have no experience in launching or selling a product amid pandemic conditions. COVID-19 also may have an adverse impact on the economies and financial markets of many

countries, including the United States, potentially resulting in an economic downturn that could affect demand for our product candidates, if approved, impair our ability to raise capital when needed or otherwise impact our business, results of operations, cash flows and financial condition. In addition, if the spread of COVID-19 continues and our operations are impacted, we risk a delay, default and/or nonperformance under our existing agreements arising from force majeure. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which health epidemics such as COVID-19 could adversely impact our business. Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change.

We are dependent on the success of our lead compound, lirentelimab, which is currently in multiple clinical trials. If we are unable to obtain approval for and commercialize lirentelimab for one or more indications in a timely manner, our business could be materially harmed.

Our future success is dependent on our ability to timely complete clinical trials and obtain marketing approval for, and then successfully commercialize lirentelimab, our lead compound, for one or more indications. Lirentelimab is in the clinical stages of development and we are investing the majority of our efforts and financial resources in the research and development of lirentelimab for multiple indications. Lirentelimab will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval from government regulators, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote lirentelimab, or any other product candidates, before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of lirentelimab will depend on several factors, including the following:

- successful and timely completion of our clinical trials of lirentelimab;
- initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- efficacy, safety and tolerability profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals for lirentelimab from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers;
- the maintenance of existing or the establishment of new scaled production arrangements with third-party manufacturers to obtain finished products that are appropriately packaged for sale;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio, including our licensed intellectual property;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. In particular, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment may also be affected by other factors, including:

- travel and other restrictions due to pandemics such as COVID-19;
- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- continued enrollment of prospective patients by clinical trial sites.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. The COVID-19 global pandemic has created uncertainties in the expected timelines for clinical stage biotechnology companies such as us, and because of such uncertainties, it is extremely difficult for us to accurately predict at this time if we can continue to enroll patients and when we can complete our Phase 3 clinical trial. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates.

The clinical trials of our product candidates may not demonstrate safety and efficacy to the satisfaction of regulatory authorities or otherwise produce positive results.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

We do not know whether our future clinical trials will begin on time or enroll patients on time, or whether our ongoing and/or future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining approval to commence a trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;

- obtaining institutional review board approval at each clinical trial site;
- recruiting suitable patients to participate in a trial;
- patients failing to comply with trial protocol or dropping out of a trial;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- the need to add new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of marketing approval or our ability to commercialize our product candidates, including:

- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain drug development programs;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;
- the cost of clinical trials of our product candidates being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate; and
- regulators revising the requirements for approving our product candidates.

If any of these events occur, we may incur unplanned costs, be delayed in obtaining marketing approval, if at all, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements or have the drug removed from the market after obtaining marketing approval.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities.

We currently have no drugs approved for sale and we cannot guarantee that we will ever have marketable drugs. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future larger registration clinical trials will be successful. This is because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. In particular, no compound with the mechanism of action of lirentelimab has been commercialized, and the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later-stage clinical trials.

From time to time, we may publish or report interim or preliminary data from our clinical trials. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and 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. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. In addition, we use patient-reported outcome assessments in our clinical trials, which involve patients' subjective assessments of efficacy of the treatments they receive in the trial. Such assessments can vary widely from day to day for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

Our product candidates may not achieve adequate market acceptance among physicians, hospitals, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, hospitals, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in planned clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our products, if approved, such as boxed warnings or contraindications in labeling, or a Risk Evaluation and Mitigation Strategy ("REMS"), if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-parties and government authorities;
- relative convenience and ease of administration;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to the product candidate; and
- the approval of other new therapies for the same indications.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be harmed. Lirentelimab is administered intravenously in our lead Phase 3 and Phase 2/3 ongoing studies. Intravenous drugs are less convenient for patients than some other methods of administration, such as an orally delivered drug.

The sizes of the patient populations suffering from some of the diseases we are targeting are small and based on estimates that may not be accurate.

Our projections of both the number of people who have some of the diseases we are targeting, as well as the subset of people with these diseases who have the potential to benefit from treatment with lirentelimab and any other future product candidates, are estimates. These estimates have been derived from a variety of sources, including

scientific literature, surveys of clinics, physician interviews, patient foundations and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for lirentelimab and any other future product candidates may be limited or may not be amenable to treatment with lirentelimab and any other products, if and when approved. Even if we obtain significant market share for lirentelimab and any other products (if and when they are approved), small potential target populations for certain indications means we may never achieve profitability without obtaining market approval for additional indications.

Our business will be impacted by our ability to advance additional product candidates beyond lirentelimab into clinical development and through to regulatory approval and commercialization. Our other product candidates are at even earlier stages of development than lirentelimab and may fail in development or suffer delays that adversely affect their commercial viability.

Our other product candidates are in the early stages of development and may fail in development or suffer delays that adversely affect their commercial viability. A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later-stage clinical trials of the product candidate.

Our future operating results are dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize other product candidates in addition to lirentelimab. The success of any product candidates we may develop will depend on many factors, including, among other things, the following:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials;
- the timely manufacture of sufficient quantities of the product candidate for use in clinical trials; and
- adverse events in the clinical trials.

Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, we cannot assure you that we will ever be able to develop, obtain regulatory approval of, commercialize or generate significant revenue from any other product candidates.

Any drugs we develop may become subject to unfavorable third-party reimbursement practices and pricing regulations.

The availability and extent of coverage and adequate reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. In the United States, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. 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 payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical drug products. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific drug products on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

If our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The biotechnology industry is highly competitive and subject to rapid and significant technological change. Products we may develop in the future are likely to face competition from other drugs and therapies, some of which we may not currently be aware. In addition, our products may need to compete with off-label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

We are not aware of any other company or organization that is conducting clinical trials of a product candidate that targets both eosinophils and mast cells, including any product candidate that specifically targets Siglec-8. The competition we may face with respect to the indications we are targeting with lirentelimab includes, without limitation, Regeneron, AstraZeneca, Bristol Meyers Squibb, Shire, and Dr. Falk Pharma for EGIDs, Blueprint

Medicines for ISM, Roche, Novartis, Regeneron, Celldex and Gossamer Bio for CU and Aldeyra for SAC. In addition, we are currently evaluating a host of other indications, and if we were to initiate trials in any such indication, we would likely face significant competition from a number of additional competitors. These companies, or other major multinational pharmaceutical and biotechnology companies, emerging and start-up companies, universities and other research institutions, could focus their future efforts on developing competing therapies and treatments for any of the indications we are currently targeting or may target in the future. Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA or foreign regulatory authorities or discovering, developing and commercializing products in our field before we do.

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

We have limited resources and are currently focusing our efforts on developing lirentelimab for particular indications. As a result, we may fail to capitalize on other product candidates or indications that may ultimately have proven to be more profitable.

We are currently focusing our efforts on a small number of indications. As a result, we may forego or delay pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development activities for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target markets for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. 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 manufacturing processes and facilities or our marketing programs. FDA investigation could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they 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 and substantial monetary awards to trial participants or patients. 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, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

The regulatory approval processes of the FDA, European Medicines Agency ("EMA") and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

The time required to obtain approval by the FDA, EMA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA, EMA and comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. We have not submitted for, or obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval in an initial or subsequent indication for many reasons, including but not limited to the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application ("BLA") or New Drug Application ("NDA"), or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- 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.

Our development program is studying patients with eosinophilic gastritis ("EG") and/or eosinophilic duodenitis ("EoD"). Varied terminology had been used in the literature to describe mucosal eosinophilia in the stomach and duodenum (including eosinophilic gastritis, eosinophilic duodenitis, eosinophilic gastroenteritis and eosinophilic enteritis), and the nomenclature for grouping non-esophageal eosinophil gastrointestinal disorders ("EGIDs"), both within the medical industry and the relevant regulatory agencies, as well as the ultimate indication and label for lirentelimab, have yet to be finalized/agreed upon. For example, in a recent communication with the FDA, they commented that they believe further characterization of isolated EoD is needed to determine whether this condition is a subtype of EG or whether it should be considered a distinct indication. The FDA stated they were

taking this position because the field of eosinophilic gastrointestinal diseases is advancing rapidly and that data from published literature, the academic community, and your development program would be informative. It is possible based on our communications that the FDA may determine EoD or any other subset of EGIDs are not separate disease processes. If the FDA determines that EoD is not a separate disease process, but the EoD population is included in the approval as a subset of an approved condition, then such a determination could cause confusion and adversely impact doctors' ability or willingness to prescribe our medication. In addition, if any particular subset of the EGID population falls outside the label, our marketing authorization would not extend to that population, which would impact the potential addressable market for our drug. Ultimately, whether lirentelimab will be used to treat any subset of EGID patients will depend on the agency's view of the efficacy and safety of lirentelimab, and our overall clinical development program.

The lengthy regulatory approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

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, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs and therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must 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, time-consuming, uncertain and subject to unanticipated delays. For example, despite the recent completion of our Phase 2 clinical trial in patients with EG and/or EoD, significant regulatory hurdles remain, both near term and long term, before lirentelimab can obtain regulatory approval in the United States. There can be no assurance we will be able to successfully conclude these undertakings in a timely manner, and it is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us to begin selling them.

Our company has not conducted or managed clinical trials through regulatory approval, including FDA approval. 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. The standards that the FDA and its foreign counterparts use when regulating us 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 or due to any delays in FDA regulatory review due to the COVID-19 outbreak. Examples of such regulations include future legislation or administrative action, or 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.

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of a BLA or NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or biologic. 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 limit the size of the market for the product 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.

Our clinical trials may reveal significant adverse events, toxicities or other side effects and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

In order to obtain marketing approval for any of our product candidates, we must demonstrate the safety and efficacy of the product candidate for the relevant clinical indication or indications through preclinical studies and clinical trials as well as additional supporting data. If our product candidates are associated with undesirable side effects in preclinical studies or clinical trials, or have unexpected characteristics, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

We have conducted Phase 1 and Phase 2 clinical trials in healthy volunteers, as well as in patients with EG, EoD, CU, ISM and SAC. However, we do not know the predictive value of these trials for our future clinical trials, and we cannot guarantee that any positive results in preclinical studies or previous clinical trials will successfully translate to patients in our future clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical testing, and many product candidates fail in clinical trials despite promising preclinical results. 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 have nonetheless failed to obtain marketing approval for their products. Because Siglec-8 is only naturally expressed in humans and certain other primates, there is no standard animal toxicology model for anti-Siglec-8 therapies, and the acceptability of our preclinical safety data for lirentelimab depends on the continued acceptance by the FDA and EMA, and the acceptance by other regulatory authorities, of the use of our proprietary transgenic mice models for toxicology studies.

Lirentelimab has generally been well tolerated in our clinical trials. The most common adverse event has been the occurrence of mild to moderate infusion-related reactions (“IRRs”) (consisting of flushing, feeling of warmth, headache, nausea or dizziness) which occurred mostly, but not exclusively, during the first infusion. Temporal interruption of the lirentelimab infusion and minimal intervention generally resulted in prompt resolution of symptoms and ability to resume the infusion without further complications, although there have been instances when an IRR has resulted in a subject being discontinued from a trial. Subjects in our ongoing and planned clinical trials may in the future suffer other significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. If clinical trials of our product candidates fail to demonstrate efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, development and commercialization of our product candidates.

If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, the EMA, other applicable regulatory authorities or an institutional review board may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability relative to other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with our product candidates may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional warnings being added to the labeling, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities

in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical testing.

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

We currently conduct clinical trials both in the United States and in other countries. We may in the future choose to conduct additional clinical trials in countries outside the United States, including in Europe. The acceptance of study data by the FDA, EMA or applicable 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 and (ii) the trials are performed by clinical investigators of recognized competence and pursuant to current good clinical practices regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance 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 or clearance for commercialization in the applicable jurisdiction.

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

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

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any partner we work with fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements.

Any regulatory approvals that we may receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements, such as boxed warning on the packaging, to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates 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 current good manufacturing practices ("cGMPs") and good clinical practices ("GCPs"), for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and foreign regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending BLAs or supplements to approved BLAs.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue.

We may not be able to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving competing products.

Regulatory authorities in some jurisdictions, including the U.S. and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S., or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. We have obtained orphan drug designation for EG, EoD and EoE in the U.S. and for ISM in the U.S. and European Union and we may seek orphan drug designations for other indications or for other of our product candidates. There can be no assurances that we will be able to obtain such designations.

In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the U.S. provides that the FDA may not approve any other applications, including a full BLA or NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug designation for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the U.S. may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Given the FDA's stated uncertainty surrounding EGID diseases, it is possible the FDA could decide EGIDs in general, or any subset of the EGID population, is a much larger market and accordingly ineligible for orphan drug status. We have obtained orphan drug designation for EG, EoD and EoE in the U.S. but further redefinitions of the EGID diseases by the FDA could cause us to lose such status. Were this to occur, we would not only lose the financial incentives and exclusivity granted to orphan drugs, we could also be forced to undertake larger or additional clinical trials which could impact our proposed timeline for introducing lirentelimab and impact our business, financial condition and results of operations.

Although we may seek a breakthrough therapy designation for lirentelimab or one or more of our other product candidates, we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may seek a breakthrough therapy designation for lirentelimab in one or more indications or for other product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive breakthrough therapy designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may face difficulties from changes to current regulations and future legislation.

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 U.S. 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.

Certain members of Congress have made various efforts to repeal all or portions of the Affordable Care Act ("ACA"), including suspending the penalties for failing to comply with the individual insurance mandate, removing funds designed to drive enrollment in the program, repealing the "Cadillac tax" on certain high-cost, employee-sponsored health insurance plans and coming within a single vote in the U.S. Senate of repealing the ACA altogether. There is uncertainty with respect to the impact future actions by Congress or the courts may have and any changes likely will take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any further healthcare reform legislation or the impact of potential legislation on us. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2025 unless additional Congressional action is taken. 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.

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. For example, President Biden made drug price reform a focal point of his 2020 presidential campaign. 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 sufficient revenue, attain profitability or commercialize our product candidates.

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 the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

If we fail to comply with applicable U.S. and foreign privacy and data protection laws and regulations, we may be subject to liabilities that adversely affect our business, operations and financial performance.

We are subject to federal and state laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, federal and state security breach notification laws, state health information privacy laws and federal and state consumer protection laws impose requirements regarding the collection, use, disclosure and storage of personal information. In addition, in June 2018, California enacted the California Consumer Privacy Act (the "CCPA"), which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, and HIPAA protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. Additionally, the California Privacy Rights Act, amending and expanding CCPA, was passed via ballot initiative during the November 2020 election, which will further strengthen privacy laws in California and create a new privacy regulatory agency in the state. The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

We may also be subject to or affected by foreign laws and regulations, including regulatory guidance, governing the collection, use, disclosure, security, transfer and storage of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials and our other operations in the U.S. and abroad. The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This

evolution may create uncertainty in our business, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. For example, the EU has adopted the General Data Protection Regulation (the "GDPR"), which introduces strict requirements for processing personal data. The GDPR increases our compliance burden with respect to data protection, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and leverage information about them. The processing of sensitive personal data, such as information about health conditions, entails heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for breach reporting requirements, more robust regulatory enforcement and fines of up to the greater of 20 million euros or 4% of annual global revenue. While companies are afforded some flexibility in determining how to comply with the GDPR's various requirements, significant effort and expense are required to ensure continuing compliance with the GDPR. Moreover, the requirements under the GDPR and guidance issued by different EU member states may change periodically or may be modified, and such changes or modifications could have an adverse effect on our business operations if compliance becomes substantially costlier than under current requirements. For example, on July 16, 2020, the Court of Justice of the European Union invalidated the EU-US Privacy Shield Framework under which personal data could be transferred from the EEA to United States entities that had self-certified under the Privacy Shield scheme. It is currently unclear what additional measures will need to be put in place as a result of this court ruling. It is also possible that each of these privacy laws may be interpreted and applied in a manner that is inconsistent with our practices. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort, proceedings against us by governmental entities or others, and fines. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with 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 products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute 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 a federal healthcare program such as Medicare and Medicaid;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, 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;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information was made publicly available on a searchable website in September 2014 and will be disclosed on an annual basis; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, 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 biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. 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.

Efforts to ensure that our current and future business arrangements with third-parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. 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. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

Our success is highly dependent on the services of our Chief Executive Officer, Dr. Robert Alexander, and our President, Chief Operating Officer and Chief Financial Officer, Dr. Adam Tomasi, and our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff, particularly our Chief Executive Officer, Dr. Robert Alexander, and our President, Chief Operating Officer and Chief Financial Officer, Dr. Adam Tomasi. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers, including Dr. Alexander or Dr. Tomasi, could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. In addition to competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may

provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

If we are unable to establish sales or marketing capabilities or enter into agreements with third-parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We currently have a small commercial team which will need to be expanded substantially to support the marketing, sales and distribution of any of our product candidates that may be able to obtain regulatory approval. In order to commercialize any product candidates, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third-parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third-parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third-parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third-parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third-parties, our future product revenue will suffer and we may 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.

At December 31, 2020, we had 125 full-time employees, including 87 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for lirentelimab and any other future product candidates, while complying with any contractual obligations to contractors and other third-parties we may have; 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 lirentelimab and any other 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.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including most aspects of clinical management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or

accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of lirentelimab and any other future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers 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/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize lirentelimab and any other future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.

Our success depends in significant part on our and our current or future licensors' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have developed. We have also licensed from third-parties rights to patent portfolios. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we have licensed, and other licenses may not give us such rights.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current and future licensors will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, 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 and are reliant on our current and future licensors. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current and future licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are highly uncertain. Our and our current or future licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our current and future licensors to narrow the scope of the claims of our or our current and future licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained.

We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third-parties may initiate an opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our current or future licensors' patent applications cannot be enforced against third-parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our current and future licensors were

the first to file any patent application related to a product candidate. Furthermore, if third-parties have filed such patent applications on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third-parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third-parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third-parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. In addition, 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 from its earliest U.S. filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including biosimilar or generic medications. For example, some of the patents that we exclusively licensed from The Johns Hopkins University will expire in 2021, one of our owned patent families that claims one of the product candidates will expire in 2035 in the United States and similar patent applications are pending in foreign jurisdictions with a projected expiration date in 2034, at which time the underlying technology covered by such patents can be used by any third-party, including competitors. Although the patent term extensions under the Hatch-Waxman Act in the United States may be available to extend the patent term, we cannot provide any assurances that any such patent term extension will be obtained and, if so, for how long.

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. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent. However, the applicable authorities, including the FDA and the U.S. Patent and Trademark Office ("USPTO") in the United States, and any equivalent foreign regulatory authority, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us and our current and future licensors to stop the infringement of our and our current or future licensors' patents or marketing of competing products in violation of our and our current or future licensors' proprietary rights generally. Proceedings to enforce our and our current or future licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our and our current or

future licensors' efforts and attention from other aspects of our business, could put our and our current or future licensors' patents at risk of being invalidated or interpreted narrowly and our and our current or future licensors' patent applications at risk of not issuing and could provoke third-parties to assert claims against us or our current and future licensors. We or our current and future licensors may not prevail in any lawsuits that we or our current and future licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

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 our current and future licensors are forced to grant a license to third-parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act ("Leahy-Smith Act"), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. After March 15, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, 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 patents that we might obtain in the future.

Obtaining and maintaining our 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.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our current and future licensors fail to

maintain the patents and patent applications covering our product candidates, our patent protection could be reduced or eliminated and our competitors might be better able to enter the market with competing products.

If our trademark and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected.

We cannot assure you that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. In addition, we do not own any registered trademarks for the mark "ALLAKOS." We cannot assure you that any future trademark applications that we will file will be approved. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before 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 proceeding may be filed against our trademarks and our trademarks may not survive such proceedings, which may force us to rebrand our name.

If we breach the license agreements related to our product candidates, we could lose the ability to continue the development and commercialization of our product candidates.

Our commercial success depends upon our ability, and the ability of our current and future licensors, to develop, manufacture, market and sell our product candidates and use our and our current or future licensors' wholly-owned technologies without infringing the proprietary rights of third-parties. A third-party may hold intellectual property, including patent rights that are important or necessary to the development of our products. As a result, we are a party to a number of technology licenses that are important to our business. For example, we have obtained an exclusive license under certain intellectual property related to Siglec-8 from The Johns Hopkins University to develop certain products and a non-exclusive license from BioWa and Lonza to develop and commercialize products manufactured in a particular mammalian host cell line. If we fail to comply with the obligations under these agreements, including payment and diligence terms, our current and future licensors may have the right to terminate these agreements, in which event we may not be able to develop, manufacture, market or sell any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under any collaboration relationships we might enter into in the future;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current and future licensors and us; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Third-parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third-parties to challenge the validity or scope of intellectual property rights controlled by third-parties, the outcome of which would be uncertain and could have an adverse effect on the success of our business.

Third-parties may initiate legal proceedings against us or our current and future licensors alleging that we or our current and future licensors infringe their intellectual property rights, or we or our current and future licensors may initiate legal proceedings against third-parties to challenge the validity or scope of intellectual property rights controlled by third-parties, including in oppositions, interferences, reexaminations, *inter partes* reviews or derivation proceedings in the United States or other jurisdictions. These proceedings can be expensive and time-consuming, and many of our or our current and future licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our current and future licensors.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. An unfavorable outcome could require us or our current and future licensors to cease using the related technology or developing or commercializing our product candidates, 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 or our current and future licensors a license on commercially reasonable terms or at all. Even if we or our current and future licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our current and future licensors. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business.

We may be subject to claims by third-parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at other biopharmaceutical companies, including potential competitors. Some of these employees executed proprietary rights, non-disclosure and/or non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third-party, and we could be required to obtain a license from such third-party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Trade secrets can be difficult to protect. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, contract manufacturers, consultants, advisors and other third-parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of the 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. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent information and techniques and we cannot guarantee that our competitors will not independently develop substantially equivalent information and techniques. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us. Failure on our part to adequately protect our trade secrets and our confidential information would harm our business and our competitive position.

Risks Related to Our Dependence on Third-Parties

We rely on third-parties to conduct our clinical trials and those third-parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.

We do not have the ability to independently conduct our clinical trials. We currently rely on third-parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials of lirentelimab and expect to continue to rely upon third-parties to conduct additional clinical trials of lirentelimab and our other product candidates. Third-parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third-parties are not our employees, and except for remedies available to us under our agreements, we have limited ability to control the amount or timing of resources that any such third-party will devote to our clinical trials. Some of these third-parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our drug development activities.

Our reliance on these third-parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

The third-parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. If these third-parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We contract with third-parties for the production of our product candidates for preclinical studies and, in the case of lirentelimab, our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third-parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party

manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. In the case of lirentelimab, we rely on a single third-party manufacturer, Lonza, and we currently have no alternative manufacturer in place. If we were to experience an unexpected loss of supply of lirentelimab, or any of our other product candidates, for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, including issues related to the COVID-19 global pandemic, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. Replacement of our sole manufacturer of lirentelimab would result in substantial delay and interrupt our clinical trials involving lirentelimab.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain required agreements with third-party manufacturers or to do so on acceptable terms. Reliance on third-party manufacturers entails additional risks, including:

- the possible failure of the third-party to manufacture our product candidate 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 possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the possible breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the possible failure of the third-party to manufacture our product candidates according to our specifications;
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of 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 possible misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners, including Lonza, for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers, including Lonza, cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our drugs and harm our business and results of operations.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis.

We may not gain the efficiencies we expect from further scale-up of manufacturing of lirentelimab, and our third-party manufacturers may be unable to successfully scale-up manufacturing in sufficient quality and quantity for lirentelimab or our other product candidates, which could delay or prevent the conducting of our clinical trials or the development or commercialization of our other product candidates.

Our third-party manufacturer, Lonza, is currently manufacturing lirentelimab at a scale that is sufficient for us to complete our planned clinical trials and, if we receive marketing approval, to launch lirentelimab for the indications we are currently targeting. However, we may consider increasing the batch scale to gain cost efficiencies. If Lonza is unable to scale-up the manufacture of lirentelimab at such time, we may not gain such cost efficiencies and may not realize the benefits that would typically be expected from further scale-up of manufacturing of lirentelimab.

In addition, in order to conduct clinical trials of any of our other product candidates, we may need to manufacture them in large quantities. Our third-party manufacturers, including Lonza, may be unable to successfully increase the manufacturing capacity for any of these product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our third-party manufacturers are unable to successfully scale up the manufacture of our other product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

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

As product candidates progress through preclinical and late stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

The manufacture of biologics is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing biologics, especially in large quantities, is complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. Lonza, our current third-party manufacturer, has, and our future third-party manufacturers may have, multiple locations at which they conduct manufacturing. However, lirentelimab and our other product candidates are currently only being manufactured at a few of Lonza's locations. If these locations become unavailable at their anticipated capacities or the location of the manufacture of lirentelimab or our other product candidates is changed for any reason, including for reasons related to the COVID-19 global pandemic, it could result in a delay or disruption to the manufacturing process or lead to difficulties that we did not experience at the original manufacturing locations. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. If our manufacturers

are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

If we decide to establish collaborations, but are not able to establish those collaborations, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third-parties.

We would face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, 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. Employee misconduct could 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. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, 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 comply with these 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 significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Related to Ownership of Our Common Stock

The market price of our stock may continue to be volatile, which could result in substantial losses for investors.

The trading price of our common stock has been, and is likely to continue to be, highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. We priced our initial public offering at $18.00 per share on July 19, 2018, and our common stock reached a high of $157.98 per share during the first quarter of 2021. As of February 23, 2021, the closing price of our common stock was $119.52. The trading price of our common stock could be subject to wide fluctuations in response to various factors, which in addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, include:

- the timing and results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors' products;
- impacts and developments in the COVID-19 pandemic;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions.

In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including in response to the COVID-19 pandemic. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration

agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- delays or increased costs related to the COVID-19 global pandemic;
- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical trials for lirentelimab and any of our future product candidates or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- competition from existing and potential future products that compete with lirentelimab and any of our future product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of lirentelimab or any of our future product candidates;
- the level of demand for lirentelimab and any of our future product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with lirentelimab and any of our future product candidates;
- our ability to commercialize lirentelimab and any of our future product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or

investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

Raising additional capital may restrict our operations or require us to relinquish rights to our technologies or product candidates, and if we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, partnerships and marketing, distribution or licensing arrangements. We do not have any committed external source of funds. We may also from time to time issue additional shares of common stock at a discount from the then current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our stockholders would experience additional dilution and, as a result, our stock price may decline. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through partnerships or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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.

As of December 31, 2020, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 88.5% of our outstanding voting stock. As a result, this group of stockholders has the ability to significantly influence all matters requiring stockholder approval, including the election of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We are currently and may in the future be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We are currently and may in the future be the target of this type of litigation. For example, on March 10, 2020, a putative securities class action complaint captioned Kim v. Allakos et al., No. 20-cv-01720 (N.D. Cal.) was filed in the United States District Court for the Northern District of California against us, our Chief Executive Officer, Dr. Robert Alexander, and our former Chief Financial Officer, Mr. Leo Redmond. The complaint asserts claims for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder and seeks damages based on alleged material misrepresentations and omissions concerning our Phase 2 clinical trials of lirentelimab. The proposed class period is August 5, 2019, through December 17, 2019, inclusive. This or other securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We have not paid and do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion 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 their stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a "poison pill");
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware ("DGCL"), prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and 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 the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;

- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (such provision, the "Federal Forum Provision"). However, on December 19, 2018, the Delaware Court of Chancery issued a decision in Matthew Sciabacucchi v. Matthew B. Salzberg et al., C.A. No. 2017-0931-JTL (Del. Ch.), finding that such provisions such as the Federal Forum Provision are not valid under Delaware law. In light of this decision of the Delaware Court of Chancery, we do not intend to enforce the federal forum provision in our amended and restated certificate of incorporation unless and until such time there is a final determination by the Delaware Supreme Court regarding the validity of such provisions. If the decision is not appealed or if the Delaware Supreme Court affirms the Delaware Chancery Court's decision, then we will seek approval by our stockholders to amend our certificate of incorporation at our next regularly-scheduled annual meeting of stockholders to remove the Federal Forum Provision.

These exclusive-forum provisions 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 lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

General Business Risks

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

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

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

In addition, 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 commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business activities may be subject to the Foreign Corrupt Practices Act ("FCPA"), the UK Bribery Act 2010 ("UK Bribery Act"), and other similar anti-bribery and anti-corruption laws of other countries in which we operate.

We have conducted and have ongoing studies in international locations, and may in the future initiate additional studies in countries other than the U.S. Our business activities may be subject to the FCPA, the UK Bribery Act and other similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which

we operate. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

We may experience disruptions and delays or incur financial damages as a result of system failures or security breaches.

Despite the implementation of security measures, any of the internal computer systems belonging to us or our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. Any system failure, accident or security breach that causes interruptions in our own or in third-party service providers' operations could result in a material disruption of our drug discovery and development programs. A system failure or security breach that causes the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs in order to recover or reproduce the lost data. In addition, to the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability as a result, our drug discovery programs and competitive position may be adversely affected, and further development of our product candidates may be delayed. Any such disruption, failure or security breach could also cause us to incur additional costs to remedy the damages that arise from such disruption, failure or security breach.

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.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, 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 or our business. If any of the analysts covering us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. In addition, 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 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 Securities Exchange Act of 1934, as amended ("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.

Our operations are vulnerable to interruption by fire, earthquake, power loss, telecommunications failure, terrorist activity and other events beyond our control, which could harm our business.

Our facility is located in a seismically active region and in a state which also experiences large scale wildfires from time to time. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity or other disasters and do not have a recovery plan for such disasters. In addition, we are in the process of constructing a new office and laboratory facility in San Carlos, California pursuant to a lease agreement we entered into in December 2019. We may encounter difficulties and delays in construction as well as in obtaining necessary validation, permits, licenses, and certifications for this facility. For example, as circumstances around the COVID-19 pandemic are evolving, government-imposed quarantines and restrictions may require us to temporarily halt construction or validation activities. Furthermore, we may not be able to fully occupy this facility on our currently anticipated timeline, which

could negatively impact our financial results given the fixed costs associated with the lease. If we are unable to complete construction in a timely and satisfactory manner, obtain the necessary permits, licenses, certificates, and accreditations or fully occupy this facility, we may be unable to meet our currently anticipated development timelines for our product candidates, which would negatively impact our reputation, commercial plans and results of operations.

In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. We maintain multiple copies of each of our antibody sequences and electronic data records, most of which we maintain at our headquarters. If our facility were impacted by a seismic event, we could lose all our antibody sequences, which would have an adverse effect on our ability to discover new targets.

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

As of December 31, 2020, we had gross U.S. federal and state net operating loss carryforwards of $399.9 million and $48.1 million , respectively. Federal net operating loss carryforwards of $338.0 million, which were generated after December 31, 2017, do not expire. The remaining $61.9 million of federal net operating loss carryforwards expire beginning in 2032. It is possible that we will not generate taxable income in time to use our net operating loss carryforwards before their expiration (if applicable) or at all. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage points change (by value) in the ownership of its equity over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. We have not yet undertaken an analysis under Sections 382 and 383 of the Internal Revenue Code to see if any of our net operating loss carryforwards were limited as a result of our prior stock sales, including those made as part of our initial public offering. As a result, we may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Accordingly, our ability to utilize our net operating loss carryforwards and certain other tax attributes could be limited by an "ownership change" as described above, which could result in increased tax liability to our company.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters are currently located in Redwood City, California, where we lease 25,136 square feet of office, research and development and laboratory space pursuant to a lease agreement that commenced on November 1, 2018 and expires on July 31, 2029, with an option to extend for five years.

On December 4, 2019, we entered into a lease agreement for approximately 98,000 square feet of office space to be constructed in San Carlos, California. These premises were delivered in November 2020, and we expect to move into this new headquarters in the second half of 2021 after making certain improvements. The lease term will expire 123 months following the rent commencement date, which is expected to be the earlier of nine months after the premises are delivered or the date our tenant improvements are substantially completed. This lease agreement includes an option to extend the term for an additional period of five years and provides us a right of first refusal for certain additional office space.

We believe that our facilities will be sufficient for our needs over the next twelve months. We may need additional space as we expand our business and believe that additional space when needed, will be available on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. On March 10, 2020, a putative securities class action complaint captioned Kim v. Allakos et al., No. 20-cv-01720 (N.D. Cal.) was filed in the United States District Court for the Northern District of California against us, our Chief Executive Officer, Dr. Robert Alexander, and our former Chief Financial Officer, Mr. Leo Redmond. The complaint asserts claims for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder and seeks damages based on alleged material misrepresentations and omissions concerning its Phase 2 clinical trials of lirentelimab. The proposed class period is August 5, 2019, through December 17, 2019, inclusive. On August 28, 2020, the plaintiff filed an amended complaint, adding as defendants Dr. Adam Tomasi, our President, Chief Operating Officer and Chief Financial Officer, and Dr. Henrik Rasmussen, our Chief Medical Officer. Given the early stage of this litigation matter, we cannot reasonably estimate a potential future loss or a range of potential future losses and have not recorded a contingent liability accrual as of December 31, 2020.

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.

Our common stock has been listed on the NASDAQ Global Select Market under the symbol "ALLK".

Holders of Common Stock

As of February 23, 2021, there were 43 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial owners of our common stock represented by these record holders.

Dividend Policy

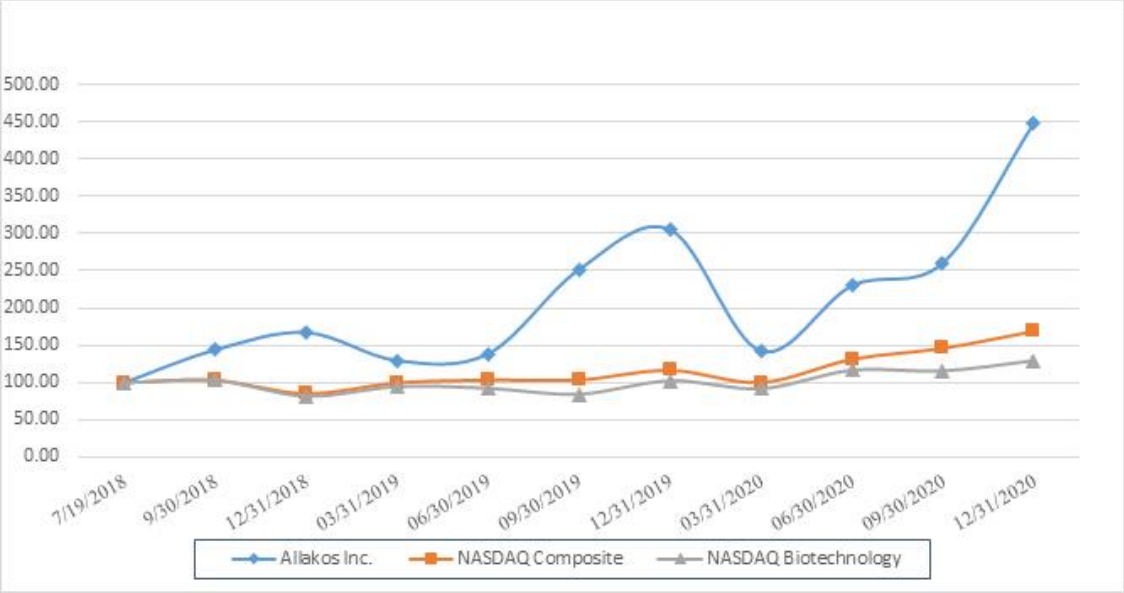
We have never declared or paid any cash dividends on our common stock or any other securities. We anticipate that we will retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future. In addition, future debt instruments may materially restrict our ability to pay dividends on our common stock. Payment of future cash dividends, if any, will be at the discretion of the board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of current or then-existing debt instruments and other factors the board of directors deems relevant.

Performance Graph

This graph below is not "soliciting material" or deemed "filed" with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to liabilities under that Section, and shall not be deemed incorporated by reference into this Annual Report on Form 10-K or into any other filing of Allakos Inc. under the Securities Act, as amended, except to the extent that we specifically incorporate this information by reference therein, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph compares the cumulative total return to stockholder return on our common stock relative to the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. An investment of $100 is assumed to have been made in our common stock and each index on July 19, 2018 (the first day of trading of our common stock) and its relative performance is tracked through December 31, 2020. Pursuant to applicable Securities and Exchange Commission rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. The stockholder returns shown on the graph below are based on historical results and are not indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

COMPARISON OF CUMULATIVE TOTAL RETURN
among Allakos Inc., the NASDAQ Composite Index
and the NASDAQ Biotechnology Index



	7/19/2018	9/30/2018	12/31/2018	3/31/2019	6/30/2019	9/30/2019	12/31/2019	3/31/2020	6/30/2020	9/30/2020	12/31/2020
Allakos Inc.	$100.00	$143.97	$ 167.26	$129.60	$138.66	$251.62	$ 305.15	$142.37	$229.95	$260.64	$ 448.00
NASDAQ Composite	100.00	103.06	85.24	99.56	103.42	103.60	116.51	100.26	131.28	146.03	168.85
NASDAQ Biotechnology	100.00	103.09	81.92	94.65	92.52	84.54	102.49	91.96	116.70	115.74	129.57

Recent Sales of Unregistered Securities

Not applicable

Use of Proceeds from Registered Securities

Not applicable

Issuer Purchases of Equity Securities

Not applicable

Item 6. Selected Financial Data.

The following tables summarize our selected financial data for the periods and as of the dates indicated. We have derived our selected statements of operations and comprehensive loss data for the years ended December 31, 2020, 2019, 2018, 2017 and 2016, and the balance sheets data as of December 31, 2020, 2019, 2018, 2017 and 2016, from our audited financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the financial and other data below in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2020	2019	2018	2017	2016
	(in thousands, except per share data)				
Statements of Operations Data:					
Loss from operations	$ (157,057)	$ (91,418)	$ (45,721)	$ (22,254)	$ (17,060)
Net loss	$ (153,480)	$ (85,372)	$ (43,538)	$ (23,552)	$ (17,100)
Net loss per share, basic and diluted (1)	$ (3.10)	$ (1.89)	$ (2.20)	$ (14.54)	$ (13.03)
Weighted-average shares of common stock outstanding, basic and diluted (1)	49,492	45,191	19,833	1,620	1,312

(1) See our statements of operations and comprehensive loss and Note 2 to our financial statements for further details on the calculation of net loss per share, basic and diluted, attributable to common stockholders and the weighted-average number of shares used in the computation of the per share amounts.

	Year Ended December 31,				
	2020	2019	2018	2017	2016
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents and marketable securities	$ 658,997	$ 495,901	$ 178,906	$ 85,207	$ 13,416
Working capital (1)	646,817	486,809	176,353	83,452	11,031
Total assets	719,618	516,894	191,259	87,029	14,176
Total liabilities	65,223	21,173	7,265	2,828	7,616
Convertible preferred stock	—	—	—	142,969	42,996
Accumulated deficit	(342,964)	(189,484)	(104,112)	(60,574)	(37,022)
Total stockholders' equity (deficit)	654,395	495,721	183,994	(58,768)	(36,436)

(1) Working capital is defined as current assets less current liabilities. See our financial statements included elsewhere in this Annual Report on Form 10-K for further details regarding our current assets and current liabilities.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the other financial information appearing elsewhere in this Annual Report on Form 10-K. These statements generally relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The following discussion and analysis contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Our actual results and the timing of events may differ materially from those discussed in our forward-looking statements as a result of various factors, including those discussed below and those discussed in the section entitled "Risk Factors" included in this Annual Report on Form 10-K. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements. Additional information concerning these and other risks and uncertainties is contained in our other periodic filings with the SEC.

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

- *risks related to the COVID-19 pandemic;*
- *our plans and ability to manufacture, or have manufactured, sufficient quantities of lirentelimab for preclinical studies and to conduct clinical trials and to eventually commercialize the product, and our reliance on third parties in relation to the foregoing;*
- *the impact that the adoption of new accounting pronouncements will have on our financial statements;*
- *the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;*
- *the timing and focus of our future clinical trials, and the reporting of data from those trials;*
- *our plans relating to commercializing lirentelimab, if approved, including the geographic areas of focus and sales strategy;*
- *the size of the market opportunity for lirentelimab in each of the diseases we are targeting;*
- *the number of diseases represented in the patient population enrolled in our clinical trials, and our ability to evaluate response to treatment of lirentelimab in diseases other than the primary indication in our clinical trials;*
- *our estimates of the number of patients in the United States who suffer from the diseases we are targeting and the number of patients that will enroll in our clinical trials;*
- *the beneficial characteristics, safety, efficacy and therapeutic effects of lirentelimab;*
- *the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for lirentelimab or our other product candidates for various diseases;*
- *our ability to obtain and maintain regulatory approval of lirentelimab or our other product candidates;*
- *our plans relating to the further development of lirentelimab and our other product candidates;*
- *existing regulations and regulatory developments in the United States and other jurisdictions;*
- *our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;*
- *our continued reliance on third-parties to conduct additional clinical trials of lirentelimab and our other product candidates;*
- *the need to hire additional personnel and our ability to attract and retain such personnel;*

- *the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;*
- *our financial performance;*
- *the sufficiency of our existing cash, cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements; and*
- *our anticipated use of the proceeds from our initial public offering and the concurrent private placement in July 2018 and subsequent follow-on offerings in August 2019 and November 2020.*

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including, but not limited to, those described in "Risk Factors." In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "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. These forward-looking statements reflect our beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report on Form 10-K and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled "Risk Factors" included in Part I, Item 1A and elsewhere in this Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible 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. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We qualify all of the forward-looking statements in this Annual Report on Form 10-K by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

Our discussion and analysis below are focused on our financial results and liquidity and capital resources for the years ended December 31, 2020 and 2019, including year-over-year comparisons of our financial performance and condition for these years. Discussion and analysis of the year ended December 31, 2018 specifically, as well as the year-over-year comparison of our financial performance and condition for the years ended December 31, 2019 and 2018, are located in Part II, Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on February 25, 2020.

Overview

We are a clinical stage biotechnology company developing lirentelimab (AK002), our wholly owned monoclonal antibody, for the treatment of various mast cell and eosinophil related diseases. Lirentelimab selectively targets both mast cells and eosinophils, two types of white blood cells that are widely distributed in the body and play a central role in the inflammatory response. Inappropriately activated mast cells and eosinophils have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. Our initial focus is on eosinophilic gastrointestinal diseases which include eosinophilic gastritis ("EG"), eosinophilic duodenitis ("EoD") which has also been referred to as eosinophilic gastroenteritis, and eosinophilic esophagitis ("EoE"); in addition, lirentelimab has the potential to treat a number of other severe diseases. Lirentelimab has received orphan disease status for EG, EoD, and EoE from the U.S. Food and Drug Administration (the "FDA"). Lirentelimab completed a randomized, double-blind, placebo-controlled Phase 2 study in patients with EG and/or EoD (see ENIGMA study results). The ENIGMA study met all prespecified primary and secondary endpoints when compared to placebo and results were published in the New England Journal of Medicine. ENIGMA patients that continued to receive lirentelimab treatment for at least 52 weeks have experienced continued symptom improvement with an average 70% reduction in EG and EoD symptoms. Additionally, patients in the ENIGMA study with co-morbid EoE showed histologic and symptomatic improvement when treated with lirentelimab compared to placebo. Based on the results from the ENIGMA study and End of Phase 2 meeting with the FDA, we began enrollment of a Phase 3 study in patients with EG and/or EoD and a Phase 2/3 study in patients with EoE. We expect results from these trials in the fourth quarter of 2021.

Despite the knowledge that mast cells and eosinophils drive many pathological conditions, there are no approved therapies that selectively target both mast cells and eosinophils. Lirentelimab binds to Siglec-8, an inhibitory receptor found on mast cells and eosinophils, which represents a novel mechanism to selectively inhibit or deplete these important immune cells and thereby potentially resolve inflammation. We believe lirentelimab is the only Siglec-8 targeting antibody currently in clinical development and may have advantages over current treatment options available to patients for the diseases we are pursuing.

Since our inception in 2012, we have devoted substantially all of our resources and efforts towards the research and development of our product candidates. Our lead product candidate, lirentelimab, a monoclonal antibody targeting Siglec-8, entered clinical trials in 2016. In addition to activities conducted internally at our facilities, we have utilized significant financial resources to engage contractors, consultants and other third parties to conduct various preclinical and clinical development activities on our behalf.

To date, we have not had any products approved for sale and have not generated any revenue nor been profitable. Further, we do not expect to generate revenue from product sales until such time, if ever, that we are able to successfully complete the development and obtain marketing approval for one of our product candidates. We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We have incurred significant operating losses to date and expect to incur significant operating losses for the foreseeable future. Our net losses were $153.5 million and $85.4 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $343.0 million.

Prior to completing our IPO in July 2018 and subsequent follow-on offerings in August 2019 and November 2020, our operations had been historically financed primarily through the private placements of convertible debt instruments and convertible preferred stock. These private placements provided gross proceeds of $146.9 million. As of December 31, 2020, we had cash, cash equivalents and marketable securities of $659.0 million, which we believe will be sufficient to fund our planned operations for at least the next 12 months from the issuance of our financial statements.

July 2018 Initial Public Offering

On July 23, 2018, we completed an IPO, selling 8,203,332 shares of common stock at $18.00 per share (the “July 2018 IPO”). Proceeds from our July 2018 IPO, net of underwriting discounts and commissions, were $137.3 million. Concurrently with our July 2018 IPO, we completed a private placement of 250,000 shares of common stock at $18.00 per share to an existing stockholder. Proceeds from this private placement were $4.5 million.

In connection with the completion of the July 2018 IPO, all then outstanding shares of convertible preferred stock converted into 30,971,627 shares of common stock.

August 2019 Follow-On Offering

On August 9, 2019, we closed an underwritten public offering (the “August 2019 Offering”) under our shelf registration statement on Form S-3 (File No. 333-233018) pursuant to which we sold an aggregate of 5,227,272 shares of our common stock at a public offering price of $77.00 per share. We received aggregate net proceeds of $377.5 million, after deducting the underwriting discounts and commissions and offering expenses.

November 2020 Follow-On Offering

On November 2, 2020, we closed an underwritten public offering (the “November 2020 Offering”) under our shelf registration statement on Form S-3 (File No. 333-233018) pursuant to which we sold an aggregate of 3,506,098 shares of our common stock at a public offering price of $82.00 per share. We received aggregate net proceeds of $271.7 million, after deducting the underwriting discounts and commissions.

Components of Operating Results

Revenue

We have not generated any revenue from product sales or otherwise, and do not expect to generate any revenue for at least the next several years.

Operating Expenses

We classify operating expenses into two categories: (i) research and development and (ii) general and administrative.

Research and Development Expenses

Research and development expenses represent the following costs incurred by us for the discovery, development and manufacturing of our product candidates:

- consultant and personnel-related costs including consulting fees, employee salaries and benefits, travel and stock-based compensation expense;
- costs incurred under service agreements with contract research organizations ("CROs") that conduct nonclinical research and development activities on our behalf;
- costs incurred under service agreements with clinical CROs and clinical investigative sites to conduct our clinical studies;
- costs incurred under service agreements with contract development and manufacturing organizations ("CDMOs") for the manufacture and fill finish of our product candidates;
- costs related to in-house research and development activities conducted at our facilities including laboratory supplies, non-capital laboratory equipment and depreciation of capital laboratory equipment and leasehold improvements;
- costs incurred under exclusive and non-exclusive license agreements with third-parties; and
- allocated facility and other costs including the rent and maintenance of our facilities, insurance premiums, depreciation of shared-use leasehold improvements and general office supplies.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as clinical site activations, patient enrollment or information provided to us by our clinical CROs and clinical investigative sites, along with analysis by our in-house clinical operations personnel. Advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized as prepaid expenses, even when there is no alternative future use for the research and development. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

Prior to the regulatory approval of our product candidates, we recognize expenses incurred with our CDMOs for the manufacture of product candidates that could potentially be available to support future commercial sales, if approved, in the period in which they have occurred. To date, we have not yet capitalized any costs to inventory as we are unable to determine if these costs will provide a future economic benefit, given the unapproved nature of our product candidates.

The successful development of our product candidates is highly uncertain. Accordingly, it is difficult to estimate the nature, timing and extent of costs necessary to complete the remainder of the development of our product candidates. We are also unable to predict when, if ever, we will be able to generate revenue from our product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty surrounding:

- demonstrating sufficient safety and tolerability profiles of product candidates;
- successful enrollment and completion of clinical trials;

- requisite clearance and approvals from applicable regulatory authorities;
- establishing and maintaining commercial manufacturing capabilities with CDMOs;
- obtaining and maintaining protection of intellectual property; and
- commercializing product candidates, if and when approved, alone or in collaboration with third-parties.

A change pertaining to any of these variables would significantly impact the timing and extent of costs incurred with respect to the development and commercialization of our product candidates.

External costs incurred from CDMOs, clinical CROs and clinical investigative sites have comprised a significant portion of our research and development expenses since inception. We track these costs on a program-by-program basis following the advancement of a product candidate into clinical development. Consulting and personnel-related costs, laboratory supplies and non-capital equipment utilized in the conduct of in-house research, in-licensing fees and general overhead, are not tracked on a program-by-program basis, nor are they allocated, as they commonly benefit multiple projects, including those still in our pipeline.

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Lirentelimab contract research and development costs	$ 55,322	$ 30,806	$ 12,990
Consulting and personnel-related costs	37,560	23,967	14,144
Other unallocated research and development costs	12,651	7,085	6,153
Total	$ 105,533	$ 61,858	$ 33,287

We anticipate that our research and development expenses will increase in the future, primarily driven by costs associated with the manufacturing of our lead product candidate, lirentelimab, as we continue to increase the frequency and scale of our manufacturing batches in anticipation of a commercial launch if we are able to obtain FDA approval. Additionally, we expect to incur increasing costs associated with the conduct of our ongoing and future late stage clinical trials.

General and Administrative Expenses

General and administrative expenses consist of fees paid to consultants, salaries, benefits and other personnel-related costs, including stock-based compensation, for our personnel in executive, finance, accounting and other administrative functions, legal costs, fees paid for accounting and tax services, costs associated with pre-commercialization activities and facility costs not otherwise included in research and development expenses. Legal costs include general corporate and patent legal fees and related costs.

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities, as well as progress on our preliminary commercial development activities, including costs related to personnel, outside consultants, attorneys and accountants, among others. Additionally, we expect to incur costs associated with continuing to operate as a public company, including expenses related to maintaining compliance with the rules and regulations of the SEC, and those of any national securities exchange on which our securities are traded, additional insurance premiums, investor relations activities and other ancillary administrative and professional services.

Interest Income

Interest income primarily consists of interest and investment income earned on our cash, cash equivalents and marketable securities included on the balance sheets.

Other Expense, Net

Other expense, net, primarily consists of amounts realized from gains and losses related to fluctuations in foreign currencies.

In-Licensing Agreements

We have entered into a number of exclusive and nonexclusive, royalty bearing license agreements with third-parties for certain intellectual property. Under the terms of the license agreements described below, we are obligated to pay milestone payments upon the achievement of specified clinical, regulatory and commercial milestones. Research and development expense associated with the Company's milestone payments are recognized when such milestone has been achieved. Actual amounts due under the license agreements vary depending on factors including, but not limited to, the number of product candidates we develop and our ability to successfully develop and commercialize our product candidates covered under the respective agreements. In addition to milestone payments, we are also subject to future royalty payments based on sales of our product candidates covered under the agreements, as well as certain minimum annual royalty and commercial reservation fees. Because the achievement of milestones and the timing and extent of future royalties is not probable, these contingent amounts have not been included on our balance sheets or as part of Contractual Obligations and Commitments discussion below.

We incurred $3.4 million of milestone expense for the year ended December 31, 2020 related to development milestones associated with the first patient dosed in our Phase 3 study with lirentelimab. We did not incur any milestone expense for the year ended December 31, 2019. We recognized $0.3 million of milestone expense for the year ended December 31, 2018 related to development milestones associated with the first patient dosed in our Phase 2 study with lirentelimab. Milestone payments are not creditable against royalties. As of December 31, 2020, we have not incurred any royalty liabilities related to our license agreements, as product sales have not yet commenced.

Exclusive License Agreement with The Johns Hopkins University

In December 2013, we entered into a license agreement with JHU for a worldwide exclusive license to develop, use, manufacture and commercialize covered product candidates including lirentelimab, which was amended in September 2016. Under the terms of the agreement, we have made upfront and milestone payments of $0.7 million through December 31, 2020 and we may be required to make aggregate additional milestone payments of up to $3.6 million. We also issued 88,887 shares of common stock as consideration under the JHU license agreement. In addition to milestone payments, we are also subject to single-digit royalties to JHU based on future net sales of each licensed therapeutic product candidate by us and our affiliates and sublicensees, with up to a low six-digit dollar minimum annual royalty payment.

Non-exclusive License Agreement with BioWa Inc. and Lonza Sales AG

In October 2013, we entered into a tripartite agreement with BioWa and Lonza for the non-exclusive worldwide license to develop and commercialize product candidates including lirentelimab that are manufactured using a technology jointly developed and owned by BioWa and Lonza. Under the terms of the agreement, we have made milestone payments of $3.4 million through December 31, 2020 and we may be required to make aggregate additional milestone payments of up to $38.0 million. In addition to milestone payments, we are also subject to minimum annual commercial license fees of $40,000 per year to BioWa until such time as BioWa receives royalty payments, as well as low single-digit royalties to BioWa and to Lonza. Royalties are based on future net sales by us and our affiliates and sublicensees and vary dependent on Lonza's participation as sole manufacturer for commercial production.

Critical Accounting Policies and Use of 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 generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of our 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 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 or conditions.

We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Accrued Contract Research and Development Expense

As part of our preparation of the financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, as well as working with internal personnel to identify the existence and extent of services that have been performed on our behalf which have not yet been invoiced. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates, recording adjustments, if necessary.

Estimates underlying accrued contract research and development expense primarily relate to our evaluation of the timing and extent of development and manufacturing services performed by our CDMOs, as well as research activities performed by CROs and clinical investigative sites activities on our behalf. As the financial terms included within service agreements with such vendors vary from contract to contract and often include uneven payment flows, our evaluation focuses on the level of effort and resources expended. Accordingly, the calculation of accrued contract research and development expense requires us to analyze a significant amount of inputs and data from multiple internal and external sources, including information from communications with clinical operations and technical operations personnel.

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 higher or lower in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred for the periods reported.

Operating Leases

Effective January 1, 2019, we account for our leases in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 842, "Leases" ("ASC 842"). As part of this transition, we elected a number of optional practical expedients made available under the ASC 842 transition guidance including (i) carrying forward the Company's historical lease classifications, (ii) foregoing of re-evaluation of historical contracts using ASC 842's definition of a lease, (iii) foregoing a re-assessment of initial direct costs related to leases that existed prior to adoption, (iv) combining lease and non-lease components for all classes of assets, and (v) recognizing lease expense for all contracts with an initial term of 12 months or less within the statements of operations and comprehensive loss on a straight-line basis over the requisite lease term.

Under ASC 842, we account for our leases by recording right-of-use assets and lease liabilities on the balance sheets. Right-of-use assets represent our right to use an underlying asset over the lease term and include any lease payments made prior to the lease commencement date and are reduced by lease incentives. Lease liabilities represent the present value of our total lease payments over the lease term, calculated using our incremental borrowing rate. In determining our incremental borrowing rate, we considered the term of the lease and our credit risk. We recognize options to extend a lease when it is reasonably certain that we will exercise such extension. We do not recognize options to terminate a lease when it is reasonably certain that we will not exercise such early termination options. We recognize lease expense on a straight-line basis over the expected lease term.

Prior to our adoption of ASC 842, we accounted for our leases in accordance with FASB ASC 840, *Leases* ("ASC 840"). Under ASC 840, rent expense is recorded on a straight-line basis over the term of the lease. Differences that exist between cash rent payments and the recognition of rent expense, such as those resulting from rent abatements or contractual escalations of future lease payments, are recorded as a deferred rent liability and recognized as adjustments to rental expense on a straight-line basis over the term of the lease. The current portion of

the deferred rent liability is included within accrued expenses and other current liabilities on our balance sheets with the remainder reported as operating lease liabilities, net of current portion. Tenant improvement allowances received are recorded as lease incentive obligations included in accrued expenses and other current liabilities and operating lease liabilities, net of current portion on our balance sheets and amortized to rent expense over the term of the lease.

Stock-Based Compensation

We account for stock-based compensation expense resulting from stock-based awards granted to employees and nonemployees in accordance with ASC 718, Compensation—Stock Compensation, ("ASC 718"). Per ASC 718, we measure the fair value of stock-based awards on the date of grant and recognize the associated compensation expense, net of impact from estimated forfeitures, over the requisite service period on a straight-line basis. The vesting period of the stock-based award has historically served as the requisite service period for the respective grants to our employees, nonemployee directors and consultants. At each subsequent reporting date, we are required to evaluate whether the achievement of any associated vesting conditions is probable and whether or not any such events have occurred that would have resulted in the acceleration of vesting.

Determining the amount of stock-based compensation expense to be recorded requires us to develop estimates of the fair value of stock options as of the date of grant. We estimate the fair value of each stock-based award using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model uses highly subjective inputs such as the fair value of our common stock, as well as other assumptions including the expected volatility of our common stock, the expected term of the respective stock-based award, the risk-free interest rate for a period that approximates the expected term of the stock-based award being valued and the expected dividend yield on our common stock over the expected term.

Expected volatility. As we do not have sufficient trading history for our common stock, we have based our computation of expected volatility on the historical volatility of a representative group of public life science companies with similar characteristics to us, including company age and stage of product development. The historical volatility data is calculated based on a period of time commensurate with the expected term of the stock-based award being valued. We will continue to utilize this approach until a sufficient amount of historical information regarding the volatility of our own stock price becomes available or until other relevant circumstances change, such as our assessment that our identified entities are no longer appropriate to use as representative companies. In the latter case, more suitable, similar entities with publicly available stock prices will be incorporated in the calculation.

Expected term. In order to estimate the expected term of a stock-based award, we use the simplified method prescribed by SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. Under this approach, the expected term is presumed to be the average of the contractual term (ten years) and the vesting term (generally four years) of the stock-based award. We have not historically experienced, nor do we expect there to be substantially different exercise or post-vesting termination behavior among our employees and directors.

Risk-free interest rate. The risk-free interest rate is based on publicly available yields of U.S. Treasury instruments with maturities consistent with the expected term of the stock-based award.

Expected dividend yield. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

Income Taxes

We account for income taxes under the asset and liability method. Current income tax expense or benefit represents the amount of income taxes we expect to pay or have refunded in the current year. Our deferred income tax assets and liabilities are determined based on differences between financial statement reporting and tax basis accounting of assets and liabilities and net operating loss and credit carryforwards, which we measure using the enacted tax rates and laws that will be in effect when such items are expected to reverse. We reduce deferred income tax assets, as necessary, by applying a valuation allowance to the extent that we determined it is more likely than not that some or all of our tax benefits will not be realized.

We account for uncertain tax positions in accordance with ASC 740-10, *Accounting for Uncertainty in Income Taxes*. We assess all material positions reflected in our income tax returns, including all significant uncertain positions, for all tax years that are subject to assessment or challenge by relevant taxing authorities. Upon determining the sustainability of our positions, we measure the largest amount of benefit possessing greater than fifty percent likelihood of being realized upon ultimate settlement. We reassess such positions at each balance sheet date to determine whether any factors underlying the sustainability assertion have changed and whether or not the amount of the recognized tax benefit is still appropriate.

As of December 31, 2020, our gross deferred tax assets were $121.4 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, we have offset the total net deferred tax assets with a full valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses, ("NOLs"), which may be limited by certain rules governing changes in ownership, as defined in Section 382 of the Internal Revenue Code of 1986, as amended. Similar rules may apply under state tax laws. Our ability to use our remaining NOLs may be further limited if we experience future ownership changes.

The recognition and measurement of tax benefits requires significant judgment, especially in assessing uncertain tax positions. Judgments concerning the recognition and measurement of our tax benefits, as well as limitations surrounding their realizability, might change as new information becomes available.

Recent Accounting Pronouncements

See Note 2 to our financial statements for recently issued accounting pronouncements, including the respective effective dates of adoption and effects on our results of operations and financial condition.

Results of Operations

The following table summarizes our results of operations for the periods indicated (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Operating expenses			
Research and development	$ 105,533	$ 61,858	$ 33,287
General and administrative	51,524	29,560	12,434
Total operating expenses	157,057	91,418	45,721
Loss from operations	(157,057)	(91,418)	(45,721)
Interest income	4,313	6,201	2,375
Other expense, net	(736)	(155)	(192)
Net loss	(153,480)	(85,372)	(43,538)
Unrealized gain (loss) on marketable securities	(129)	152	(15)
Comprehensive loss	$ (153,609)	$ (85,220)	$ (43,553)

Comparison of the Years Ended December 31, 2020 and 2019

Research and Development Expenses

Research and development expenses were $105.5 million for the year ended December 31, 2020 compared to $61.9 million for the year ended December 31, 2019, an increase of $43.6 million. The period-over-period increase in research and development expenses is primarily driven by an additional $24.5 million of lirentelimab contract research and development costs. Increases to contract research and development costs were comprised of $14.7 million of incremental spend with clinical CROs and clinical investigative sites associated with the advancement of our clinical development with lirentelimab, as well as $9.8 million of incremental spend with CDMOs resulting from manufacturing activities associated with the scale up and increased production of lirentelimab as we progress closer to a potential commercial launch. Additional period-over-period increases included $13.6 million of consulting and personnel-related costs primarily associated with increased hiring of R&D personnel, $3.4 million related to a one-time in-licensing milestone expenses incurred during the current year associated with the initiation

of our Phase 3 study of lirentelimab, and $2.1 million of other unallocated research and development costs primarily related to the conduct of in-house research.

General and Administrative Expenses

General and administrative expenses were $51.5 million for the year ended December 31, 2020 compared to $29.6 million for the year ended December 31, 2019, an increase of $21.9 million. The period-over-period increase in general and administrative expenses was primarily attributable to an additional $18.0 million of personnel-related costs, including associated stock-based compensation expense. Other period-over-period changes included increases to G&A outside spend of $3.0 million related to legal costs, accounting and financial service costs, and costs incurred by our early commercial development efforts. Finally, we incurred incremental facilities and other administrative costs of $0.9 million not otherwise included in research and development expenses.

Interest Income

Interest income was $4.3 million for the year ended December 31, 2019 compared to $6.2 million for the year ended December 31, 2018, a decrease of $1.9 million. The year-over-year decrease is directly attributable to lower interest rates on our short-term investments purchased during the current year.

Other Expense, Net

There were no significant period-over-period changes in other expense, net, for the years ended December 31, 2020 and 2019.

Liquidity and Capital Resources

Sources of Liquidity

We are a clinical stage biotechnology company with a limited operating history. As a result of our significant research and development expenditures, we have generated net losses since our inception. We have financed our operations through our July 2018 IPO, August 2019 Offering and November 2020 Offering.

In connection with our July 2018 IPO, we sold 8,203,332 shares of common stock at a price of $18.00 per share. Proceeds from the July 2018 IPO, net of underwriting discounts and commissions, were $137.3 million. Concurrently with our July 2018 IPO, we completed a private placement of 250,000 shares of common stock at $18.00 per share to an existing stockholder. Proceeds from this private placement were $4.5 million.

We closed the August 2019 Offering under our shelf registration statement on Form S-3 (File No. 333-233018) pursuant to which we sold an aggregate of 5,227,272 shares of our common stock at a public offering price of $77.00 per share. We received aggregate net proceeds of $377.5 million, after deducting the underwriting discounts and commissions and offering expenses.

We closed the November 2020 Offering under our shelf registration statement on Form S-3 (File No. 333-233018) pursuant to which we sold an aggregate of 3,506,098 shares of our common stock at a public offering price of $82.00 per share. We received aggregate net proceeds of $271.7 million, after deducting underwriting discounts and commissions.

As of December 31, 2020, we had cash, cash equivalents and marketable securities of $659.0 million.

Based on our existing business plan, we believe that our current cash, cash equivalents and marketable securities will be sufficient to fund our anticipated level of operations through at least the next 12 months from the issuance of our financial statements.

Summary Cash Flows

The following table summarizes the primary sources and uses of our cash, cash equivalents, and restricted cash for the periods indicated (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Net cash used in operating activities	$ (113,924)	$ (63,012)	$ (38,450)
Net cash provided by (used in) investing activities	3,897	(311,971)	(151,047)
Net cash provided by financing activities	278,837	381,163	138,752
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 168,810	$ 6,180	$ (50,745)

Comparison of the Years Ended December 31, 2020 and 2019

Cash Used in Operating Activities

Net cash used in operating activities was $113.9 million for the year ended December 31, 2020, which was primarily attributable to our net loss of $153.5 million adjusted for net noncash charges of $1.4 million and net changes in operating cash and liabilities of $38.2 million. Noncash charges included $33.4 million in stock-based compensation expense, $2.4 million in net amortization of premiums and discounts on marketable securities, $1.5 million in depreciation and amortization expense and $0.9 million in amortization of right-of-use asset.

Net cash used in operating activities was $63.0 million for the year ended December 31, 2019, which was primarily attributable to our net loss of $85.4 million adjusted for net noncash charges of $14.9 million and net changes in operating assets and liabilities of $7.5 million. Noncash charges included $15.8 million in stock-based compensation expense, $1.5 million in depreciation and amortization expense and $0.3 million in amortization of right-of-use asset, partially offset by $2.7 million in net amortization of premiums and discounts on marketable securities.

Cash Used in Investing Activities

Net cash provided by investing activities was $3.9 million for the year ended December 31, 2020, which consisted of $546.8 million in proceeds from maturities of marketable securities, partially offset by $542.3 million for the purchases of marketable securities and $0.6 million for the purchases of property and equipment.

Net cash used in investing activities was $312.0 million for the year ended December 31, 2019, which consisted of $541.7 million for the purchases of marketable securities and $0.8 million for the purchases of property and equipment, partially offset by $231.0 million for maturities of marketable securities.

Cash Provided by Financing Activities

Net cash provided by financing activities was $278.8 million for the year ended December 31, 2020, which consisted primarily of $271.7 million in net proceeds from the issuance of common stock, $5.7 million in proceeds received from employees for the exercise of stock options and $1.5 million in proceeds from the issuance of common stock under the 2018 ESPP.

Net cash provided by financing activities was $381.2 million for the year ended December 31, 2019, which consisted primarily of $377.5 million in net proceeds from the issuance of common stock, $2.4 million in proceeds received from employees for the exercise of stock options and $1.2 million in proceeds from the issuance of common stock under the 2018 ESPP.

Funding Requirements

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise funding through private or public equity or debt financings, or other sources such as strategic collaborations. Adequate additional funding may not be available to us on acceptable terms

or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies.

The timing and amount of our capital expenditures will depend on many factors, including:

- the number and scope of clinical indications and clinical trials we decide to pursue;
- the scope and costs of commercial manufacturing activities;
- the extent to which we acquire or in-license other product candidates and technologies, if any;
- the cost, timing and outcome of regulatory review of our product candidates;
- the cost and timing of establishing sales and marketing capabilities for product candidates receiving marketing approval, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates; and
- the costs associated with being a public company.

If we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development and commercialization efforts. We may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

The issuance of additional equity securities may cause our stockholders to experience dilution. Future equity or debt financings may contain terms that are not favorable to us or our stockholders including debt instruments imposing covenants that restrict our operations and limit our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation, licensing or asset sale transactions.

Contractual Obligations and Commitments

The following table outlines our contractual obligations and commitments at December 31, 2020 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations (1)	$ 89,872	$ 2,399	$ 16,608	$ 17,619	$ 53,246
Purchase obligations (2)	144,985	68,137	76,848	—	—
Total	$ 234,857	$ 70,536	$ 93,456	$ 17,619	$ 53,246

(1) Operating lease obligations represent future lease payments due under our two lease agreements.
(2) Purchase obligations represent noncancelable amounts due to counterparties under various master service agreements.

In addition to the amounts included in the table above, we enter into contracts in the normal course of business with clinical CROs, clinical investigative sites and other counterparties assisting with our preclinical studies and clinical trials. Such contracts are generally cancellable, with varying provisions regarding termination. In the event of a contract being terminated, we would only be obligated for services received as of the effective date of the termination, along with cancellation fees, as applicable.

Off-Balance Sheet Arrangements

Since our inception, 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 Sensitivity

We are exposed to market risk related to changes in interest rates. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments, including cash equivalents, are in money market funds that invest in U.S. Treasury obligations. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Due to the short-term maturities and low credit risk profile of our balances held in money market funds, a hypothetical 10% change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities.

Foreign Currency Sensitivity

Our primary operations are transacted in U.S. Dollars, however, certain service agreements with third parties are denominated in currencies other than the U.S. Dollar, primarily the British Pound and Euro. As such, we are subject to foreign exchange risk and therefore, fluctuations in the value of the U.S. Dollar against the British Pound and Euro may impact the amounts reported for expenses and obligations incurred under such agreements. We do not currently engage in any hedging activity to reduce our potential exposure to currency fluctuations, although we may choose to do so in the future. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our financial condition or results of operations.

Item 8. Financial Statements and Supplementary Data.

ALLAKOS INC.
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Allakos Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Allakos Inc. (the Company) as of December 31, 2020 and 2019, the related statements of operations and comprehensive loss, statements of convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 26, 2021 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 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.

Accrued contract research and development expenses

Description of the Matter During 2020, the Company incurred $105.5 million of research and development expenses and accrued $4.7 million for contract research and development expenses as of December 31, 2020. As described in Note 2 to the Financial Statements, service agreements with third party service providers including contract development and manufacturing organizations ("CDMOs"), clinical contract research organizations ("CROs"), and clinical investigative sites comprise a significant component of the Company's research and development activities. External costs owed to clinical CROs and CDMOs are accrued and expensed based upon estimates of the proportion of work performed over the term of the individual clinical trial and manufacturing activities in accordance with signed agreements. Clinical investigative site accruals are recorded based on estimates of services received and efforts expended. The timing and the amount of payments required under each individual arrangement are often different from the pattern of costs actually incurred. The Company accrues the cost of the services with these third-party organizations based on the progress or stage of completion of the services measured by internal personnel.

Auditing management's accounting for accrued contract research and development expenses is especially challenging because the evaluation is dependent upon on a high-volume of data exchanged between the third-party service providers and internal clinical and manufacturing personnel. Determining the accrued amounts is based on an evaluation of the unique terms and conditions set in each agreement with the CDMOs, CROs, and clinical investigative sites. Additionally, due to the duration of clinical-related development activities and the timing of invoices received from third parties, the determination of the accrual for services incurred requires application of judgment by management. The lack of timely information related to certain manufacturing activities in determining the progress to completion of specific tasks conducted for each project can increase the risk of inaccurate assumptions applied to project completion when estimating the costs to be accrued.

How We Addressed the Matter in Our Audit We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's accounting for accrued contract research and development expenses process, including controls over management's review of activity progress in comparison to budgets and invoices received from third parties.

To test accrued contract research and development expense, our audit procedures included, among others, testing the accuracy and completeness of the inputs used in management's analysis to determine costs incurred. We also inspected terms and conditions for material vendor contracts and change orders and compared these to the cost models management used in tracking progress of service agreements. We evaluated estimated services incurred by third parties by understanding the terms and timeline of significant projects, evaluating management's estimate of work performed and costs incurred, and obtaining external confirmation of key terms and conditions for a sample of contracts. We met with internal clinical and manufacturing personnel to understand the status of significant contract research and development activities. Further, we inspected material invoices received from third parties after the balance sheet date and evaluated whether services performed prior to the balance sheet date had been properly included in the accrual.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

Redwood City, California
March 1, 2021

ALLAKOS INC.
BALANCE SHEETS
(in thousands, except per share data)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 207,177	$ 38,367
Investments in marketable securities	451,820	457,534
Prepaid expenses and other current assets	10,270	3,969
Total current assets	669,267	499,870
Property and equipment, net	8,345	8,410
Operating lease right-of-use assets	39,731	5,775
Other long-term assets	2,275	2,839
Total assets	$ 719,618	$ 516,894
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 13,960	$ 5,963
Accrued expenses and other current liabilities	8,490	7,098
Total current liabilities	22,450	13,061
Operating lease liabilities, net of current portion	42,773	8,112
Total liabilities	65,223	21,173
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 20,000 shares authorized as of December 31, 2020 and 2019; no shares issued and outstanding as of December 31, 2020 and 2019	—	—
Common stock, $0.001 par value per share; 200,000 shares authorized as of December 31, 2020 and 2019; 53,081 and 48,668 shares issued and outstanding as of December 31, 2020 and 2019, respectively	53	48
Additional paid-in capital	997,298	685,020
Accumulated other comprehensive gain	8	137
Accumulated deficit	(342,964)	(189,484)
Total stockholders' equity	654,395	495,721
Total liabilities and stockholders' equity	$ 719,618	$ 516,894

See accompanying notes to financial statements

ALLAKOS INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)

	Year Ended December 31,		
	2020	2019	2018
Operating expenses			
Research and development	$ 105,533	$ 61,858	$ 33,287
General and administrative	51,524	29,560	12,434
Total operating expenses	157,057	91,418	45,721
Loss from operations	(157,057)	(91,418)	(45,721)
Interest income	4,313	6,201	2,375
Other expense, net	(736)	(155)	(192)
Net loss	(153,480)	(85,372)	(43,538)
Unrealized gain (loss) on marketable securities	(129)	152	(15)
Comprehensive loss	$ (153,609)	$ (85,220)	$ (43,553)
Net loss per common share:			
Basic and diluted	$ (3.10)	$ (1.89)	$ (2.20)
Weighted-average number of common shares outstanding:			
Basic and diluted	49,492	45,191	19,833

See accompanying notes to financial statements

ALLAKOS INC.
STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2017	30,971	$ 142,969	2,114	$ 3	$ 1,803	$ —	$ (60,574)	$ (58,768)
Proceeds from repayment of recourse promissory note	—	—	—	—	50	—	—	50
Conversion of preferred stock upon initial public offering	(30,971)	(142,969)	30,972	30	142,939	—	—	142,969
Issuance of common stock upon initial public offering, net of offering costs of $3,466	—	—	8,453	8	138,349	—	—	138,357
Stock-based compensation expense	—	—	—	—	4,570	—	—	4,570
Issuance of common stock upon exercise of stock options	—	—	531	1	344	—	—	345
Issuance of common stock upon exercise of warrants	—	—	47	—	—	—	—	—
Vesting of restricted common stock	—	—	—	—	24	—	—	24
Unrealized loss on marketable securities, net of tax	—	—	—	—	—	(15)	—	(15)
Net loss	—	—	—	—	—	—	(43,538)	(43,538)
Balance as of December 31, 2018	—	$ —	42,117	$ 42	$ 288,079	$ (15)	$ (104,112)	$ 183,994
Stock-based compensation expense	—	—	—	—	15,764	—	—	15,764
Issuance of common stock upon exercise of stock options	—	—	1,250	1	2,447	—	—	2,448
Issuance of common stock upon 2018 ESPP purchase	—	—	74	—	1,190	—	—	1,190
Issuance of common stock upon follow-on offering, net of offering costs of $24,975	—	—	5,227	5	377,520	—	—	377,525
Vesting of restricted common stock	—	—	—	—	20	—	—	20
Unrealized gain on marketable securities, net of tax	—	—	—	—	—	152	—	152
Net loss	—	—	—	—	—	—	(85,372)	(85,372)
Balance as of December 31, 2019	—	$ —	48,668	$ 48	$ 685,020	$ 137	$ (189,484)	$ 495,721
Stock-based compensation expense	—	—	—	—	33,446	—	—	33,446
Issuance of common stock upon exercise of stock options	—	—	700	1	5,695	—	—	5,696
Issuance of common stock upon 2018 ESPP purchase	—	—	70	—	1,454	—	—	1,454
Issuance of common stock upon follow-on offering, net of offering costs of $15,813	—	—	3,506	4	271,683			271,687
Issuance of common stock upon vesting of restricted stock units	—	—	137	—	—	—	—	—
Unrealized loss on marketable securities	—	—	—	—	—	(129)	—	(129)
Net loss	—	—	—	—	—	—	(153,480)	(153,480)
Balance as of December 31, 2020	—	$ —	53,081	$ 53	$ 997,298	$ 8	$ (342,964)	$ 654,395

See accompanying notes to financial statements

ALLAKOS INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2020	**2019**	**2018**
Cash flows from operating activities			
Net loss	$ (153,480)	$ (85,372)	$ (43,538)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	33,446	15,764	4,570
Net amortization of premiums and discounts on marketable securities	2,358	(2,664)	(1,310)
Depreciation and amortization	1,545	1,508	242
Noncash lease expense	794	275	—
Accretion of tenant improvement allowance	—	—	(82)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(7,601)	463	(1,489)
Other long-term assets	—	(564)	313
Accounts payable	7,644	3,571	76
Accrued expenses and other current liabilities	900	4,077	2,063
Operating lease liabilities, net of current portion	470	(70)	705
Net cash used in operating activities	(113,924)	(63,012)	(38,450)
Cash flows from investing activities			
Purchases of marketable securities	(542,273)	(541,701)	(236,601)
Proceeds from maturities of marketable securities	546,800	230,500	92,500
Purchases of property and equipment	(630)	(770)	(6,946)
Net cash provided by (used in) investing activities	3,897	(311,971)	(151,047)
Cash flows from financing activities			
Proceeds from issuance of common stock, net of issuance costs	271,687	377,525	138,357
Proceeds from exercise of stock options, net of repurchases	5,696	2,448	345
Proceeds from issuance of common stock under 2018 ESPP	1,454	1,190	—
Proceeds from repayment of recourse promissory note	—	—	50
Net cash provided by financing activities	278,837	381,163	138,752
Net increase (decrease) in cash, cash equivalents and restricted cash	168,810	6,180	(50,745)
Cash, cash equivalents and restricted cash, beginning of period	40,642	34,462	85,207
Cash, cash equivalents and restricted cash, end of period	$ 209,452	$ 40,642	$ 34,462
Supplemental disclosures			
Noncash investing and financing items:			
Right-of-use assets obtained in exchange for lease obligations	$ 34,750	$ 6,050	$ —
Lessor funded lease incentives included in property and equipment	$ 304	$ —	$ 1,386
Property and equipment purchased in accounts payable	$ 353	$ —	$ 313
Vesting of restricted common stock subject to repurchase	$ —	$ 20	$ 24

See accompanying notes to financial statements

1. Organization and Business

Allakos Inc. ("Allakos" or the "Company") was incorporated in the state of Delaware in March 2012. Allakos is a clinical stage biopharmaceutical company focused on the development of lirentelimab for the treatment of eosinophil and mast cell related diseases. The Company's primary activities to date have included establishing its facilities, recruiting personnel, conducting research and development of its product candidates and raising capital. The Company's operations are located in Redwood City, California.

Liquidity Matters

Since inception, the Company has incurred net losses and negative cash flows from operations. During the year ended December 31, 2020, the Company incurred a net loss of $153.5 million and used $113.9 million of cash in operations. As of December 31, 2020, the Company had an accumulated deficit of $343.0 million and does not expect to experience positive cash flows from operating activities in the foreseeable future. The Company has financed its operations to date primarily through the sale of common stock. Management expects to incur additional operating losses in the future as the Company continues to further develop, seek regulatory approval for and, if approved, commence commercialization of its product candidates. The Company had $659.0 million of cash, cash equivalents and marketable securities at December 31, 2020. Management believes that this amount is sufficient to fund the Company's operations for at least the next 12 months from the issuance date of these financial statements

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements and accompanying notes.

Use of Estimates

Management uses significant judgment when making estimates related to common stock valuation and related stock-based compensation expense, accrued research and development expense and deferred tax valuation allowances. Management bases its estimates on historical experience and on various other assumptions that are 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 that are not readily apparent from other sources. Actual results could differ from those estimates under different assumptions or conditions, and those differences could be material to the financial position and results of operations.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to credit risk principally consist of cash, cash equivalents and marketable securities. These financial instruments are held in accounts at a single financial institution that management believes possesses high credit quality. Amounts on deposit with this financial institution have and will continue to exceed federally-insured limits. The Company has not experienced any losses on its cash deposits. Additionally, the Company's investment policy limits its investments to certain types of securities issued by the United States government and its agencies.

The Company is subject to a number of risks similar to that of other early-stage biopharmaceutical companies, including, but not limited to, the need to obtain adequate additional funding, possible failure of current or future clinical trials, its reliance on third-parties to conduct its clinical trials, the need to obtain regulatory and marketing approvals for its product candidates, competitive developments, the need to successfully commercialize and gain market acceptance of the Company's product candidates, its right to develop and commercialize its product candidates pursuant to the terms and conditions of the licenses granted to the Company, protection of proprietary

technology, the ability to make milestone, royalty or other payments due under licensing agreements, and the need to secure and maintain adequate manufacturing arrangements with third-parties. If the Company does not successfully commercialize or partner its product candidates, it will be unable to generate product revenue or achieve profitability.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the Company's balance sheets and which, in aggregate, represent the amounts reported in the statements of cash flows (in thousands):

	December 31,		
	2020	2019	2018
Cash and cash equivalents	$ 207,177	$ 38,367	$ 33,660
Restricted cash	2,275	2,275	802
Total	$ 209,452	$ 40,642	$ 34,462

Restricted cash at December 31, 2020 represents $2.3 million of security deposits for the lease of the Company's facilities in Redwood City, California and San Carlos, California. Both security deposits are in the form of letters of credit secured by restricted cash. Restricted cash amounts are included within other long-term assets on the Company's balance sheets.

Marketable Securities

The Company invests in marketable securities, primarily securities issued by the United States government and its agencies. The Company's marketable securities are considered available-for-sale and are classified as current assets even when the stated maturities of the underlying securities exceed one year from the date of the current balance sheet being reported. This classification reflects management's ability and intent to utilize proceeds from the sale of such investments to fund ongoing operations. Unrealized gains and losses are excluded from earnings and are reported as a component of accumulated other comprehensive gain. The cost of securities sold is determined using the specific-identification method. Interest earned and adjustments for the amortization of premiums and discounts on investments are included in interest income, net, on the statements of operations and comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on investments in marketable securities are included in other expense, net, on the statements of operations and comprehensive loss.

Fair Value Measurements

The Company accounts for fair value of its financial instruments in accordance with Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic No. 820, *Fair Value Measurements* ("ASC 820"). ASC 820 establishes a common definition for fair value, establishes a framework for measuring fair value and expands disclosures about such fair value measurements. Additionally, ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The Company measures fair value based on a three-level hierarchy of inputs, of which the first two are considered observable and the last unobservable. Unobservable inputs reflect the Company's own assumptions about current market conditions. The three-level hierarchy of inputs is as follows:

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

Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 **–** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of assets or liabilities.

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

The carrying amounts reflected in the Company's balance sheets for cash and cash equivalents, prepaid expenses and other current assets, other long-term assets, accounts payable, and accrued expenses and other current liabilities approximate fair value, due to their short-term nature. The Company's investments in marketable securities are measured at fair value in accordance with the levels above.

Property and Equipment, Net

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

Laboratory equipment – 3 to 5 years

Leasehold improvements – Shorter of remaining lease term or estimated life of the assets

Upon retirement or sale, the cost of disposed assets and their related accumulated depreciation are removed from the balance sheet. Any resulting gains or losses on dispositions of property and equipment are included as a component of other expense, net, within the Company's statements of operations and comprehensive loss. Repair and maintenance costs that do not significantly add value to the property and equipment, or prolong its life, are charged to operating expense as incurred.

Operating Leases

Effective January 1, 2019, the Company accounts for its leases in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 842, "Leases" ("ASC 842"). As part of this transition, the Company elected a number of optional practical expedients made available under the ASC 842 transition guidance including (i) carrying forward the Company's historical lease classifications, (ii) foregoing of re-evaluation of historical contracts using ASC 842's definition of a lease, (iii) foregoing a re-assessment of initial direct costs related to leases that existed prior to adoption, (iv) combining lease and non-lease components for all classes of assets, and (v) recognizing lease expense for all contracts with an initial term of 12 months or less within the statements of operations and comprehensive loss on a straight-line basis over the requisite lease term.

Under ASC 842, the Company accounts for its leases by recording right-of-use assets and lease liabilities on the balance sheets. Right-of-use assets represent the Company's right to use an underlying asset over the lease term and include any lease payments made prior to the lease commencement date and are reduced by lease incentives. Lease liabilities represent the present value of the total lease payments over the lease term, calculated using the Company's incremental borrowing rate. In determining the Company's incremental borrowing rate, consideration is given to the term of the lease and the Company's credit risk. The Company recognizes options to extend a lease when it is reasonably certain that it will exercise such extension. The Company does not recognize options to terminate a lease when it is reasonably certain that it will not exercise such early termination options. Lease expense is recognized on a straight-line basis over the expected lease term.

Prior to the Company's adoption of ASC 842, the Company accounted for its leases in accordance with FASB ASC 840, *Leases* ("ASC 840"). Under ASC 840, rent expense is recorded on a straight-line basis over the term of the lease. Differences that exist between cash rent payments and the recognition of rent expense, such as those resulting from rent abatements or contractual escalations of future lease payments, are recorded as a deferred rent liability and recognized as adjustments to rental expense on a straight-line basis over the term of the lease. The current portion of the deferred rent liability is included within accrued expenses and other current liabilities on the Company's balance sheets with remainder included within operating lease liabilities, net of current portion. Tenant improvement allowances received are recorded as lease incentive obligations included in accrued expenses and other

current liabilities and operating lease liabilities, net of current portion on the Company's balance sheets and amortized to rent expense over the term of the lease.

Accrued Research and Development Expense

Service agreements with contract development and manufacturing organizations ("CDMOs"), clinical contract research organizations ("CROs") and clinical investigative sites comprise a significant component of the Company's research and development activities. External costs for these vendors are recognized as the services are incurred. The Company accrues for expenses resulting from obligations under agreements with its third-parties for which the timing of payments does not match the periods over which the materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with CDMOs, clinical CROs, clinical investigative sites and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services.

The Company makes judgements and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to a CDMO, clinical CRO, clinical investigative site or other outside service provider, the payments are recorded within prepaid expenses and other current assets and subsequently recognized as research and development expense when the associated services have been performed. As actual costs become known, the Company adjusts its liabilities and assets. Inputs, such as the extent of services received and the duration of services to be performed, may vary from the Company's estimates, which will result in adjustments to research and development expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. The Company's historical estimates have not been materially different from actual amounts recorded.

Research and Development Expense

Research and development costs are expensed as incurred. Research and development costs include, among others, consulting costs, salaries, benefits, travel, stock-based compensation, laboratory supplies and other non-capital equipment utilized for in-house research, allocation of facilities and overhead costs and external costs paid to third-parties that conduct research and development activities on the Company's behalf. Amounts incurred in connection with license agreements, including milestone payments, are also included in research and development expense.

Advance payments for goods or services to be rendered in the future for use in research and development activities are deferred and included in prepaid expenses and other current assets. The deferred amounts are expensed as the related goods are delivered or the services are performed.

Segments

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker or decision-making group, in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker, its Chief Executive Officer, views its operations and manages its business in one operating segment operating exclusively in the United States.

Patent Costs

The Company expenses patent application and related legal costs as incurred and classifies such costs as general and administrative expenses in the statements of operations and comprehensive loss

Stock-Based Compensation

The Company accounts for its stock-based compensation in accordance with FASB ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based awards issued to employees and nonemployees to be recognized as expense in the statements of operations and comprehensive loss based on their grant date fair values. Stock-based awards issued to nonemployee consultants are accounted for based on the fair value of services to be received or of the intrinsic value of equity instruments to be issued, whichever is more reliably measured. The measurement date for awards issued to nonemployee consultants is the date of grant.

For purposes of determining the estimated fair value of stock options granted to employees and nonemployees, the Company uses the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the input of certain assumptions that involve judgment, for which changes can materially affect the resulting estimates of fair value. The assumptions used to determine the fair value of stock options granted were as follows:

Expected volatility – As there is insufficient trading history for the Company's common stock, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption.

Expected term – The Company determines the expected term in accordance with the "simplified method" described by SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term.

Risk-free interest rate – The Company bases the risk-free interest rate on United States Treasury securities with terms consistent to the expected term of the stock option being valued.

Expected dividends – The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

The fair value of restricted stock units ("RSUs") is determined using the quoted market price of the Company's common stock on the date of grant.

The Company uses historical data to estimate pre-vesting forfeitures and records stock-based compensation expense only for those awards expected to vest. To the extent that actual forfeitures differ from estimates, the difference is recorded as a cumulative adjustment in the period the estimate are revised. The Company expenses the fair value of its stock-based compensation awards to employees and nonemployees on a straight-line basis over the requisite service period, which is generally the vesting period.

Income Taxes

In December 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was signed into law. The Tax Act, among other changes, lowered the Company's federal tax rate from 34% to 21%. Based on provisions of the Tax Act, the Company remeasured its deferred tax assets and liabilities at December 31, 2017 to reflect the lower statutory tax rate, however, since the Company established a full valuation allowance to offset its deferred tax assets, there was no impact to the effective tax rate. The deferred tax remeasurement was provisional and represented our reasonable estimate within the meaning of Staff Accounting Board 118, which provided a measurement period that should not extend beyond one year from the Tax Act's enactment date for companies to complete the accounting under ASC 740. As of December 31, 2018, the Company has completed its analysis of the income tax effects of the Tax Act. The results of this analysis have been reflected in the Company's financial statements and related footnotes.

Comprehensive Loss

Comprehensive loss is defined as the change in stockholders' equity (deficit) during a period from transactions and other events and circumstances from non-owner sources. The difference between net loss and comprehensive loss for the years ended December 31, 2020, 2019 and 2018 are a result of unrealized gains and losses on the Company's investments in marketable securities included in current assets on the balance sheets.

Net Loss per Share

The Company calculates basic net loss per share by dividing the net loss attributable to common stockholders by the weighted-average shares of common stock outstanding during the period. The Company calculates diluted net loss per share after giving consideration to all potentially dilutive securities outstanding during the period using the treasury-stock and if-converted methods, except where the effect of including such securities would be anti-dilutive. Because the Company has reported net losses since inception, the effect from potentially dilutive securities would have been anti-dilutive and therefore has been excluded from the calculation of diluted net loss per share.

Basic and diluted net loss per share was calculated as follows (in thousands, except per share data):

	Year Ended December 31,		
	2020	2019	2018
Numerator:			
Net loss	$ (153,480)	$ (85,372)	$ (43,538)
Denominator:			
Weighted-average shares of common stock outstanding, basic and diluted	49,492	45,191	19,833
Net loss per share, basic and diluted	$ (3.10)	$ (1.89)	$ (2.20)

The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect for the periods indicated (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Options to purchase common stock	6,616	7,148	7,811
Unvested restricted stock units	1,161	542	—
Unvested restricted common stock	—	—	47
Shares issuable under employee stock purchase plans	14	31	29
Total	7,791	7,721	7,887

Foreign Currency Transactions

The Company is party to multiple contract manufacturing and clinical research agreements for which services to be performed are denominated in foreign currencies other than the United States Dollar. The Company records gains and losses attributable to fluctuations in foreign currencies as a component of other income (expense), net, on the statements of operations and comprehensive loss.

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. This ASU affects general principles within Topic 740 and are meant to simplify the accounting for income taxes by removing certain exceptions to the general framework. The ASU further adds guidance to reduce complexity in certain areas, including recognizing a franchise (or similar) tax that is partially based on income as an income-based tax and incremental amounts incurred as a non-income-based tax and recognizing deferred taxes for tax goodwill. ASU 2019-12 also created an exception to the incremental approach for intraperiod tax allocation when there is a loss from continuing operations and income or a gain from other items (for example, other comprehensive income). Under the historical guidance, in this situation, an entity would have recorded an income tax provision for unrealized gains on available-for-sale securities reported in other comprehensive income, with an offsetting income tax benefit recorded in continuing operations. Per ASU 2019-12, under the new guidance, an entity would record no income tax provision in the interim period. The amendments in ASU 2019-12 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption of the amendments is permitted, including adoption in any interim period for which financial statements have not yet been issued. An entity that elects to early adopt the amendments in an interim period should reflect any adjustments as of the beginning of the annual period that includes that interim period.

Additionally, an entity that elects early adoption must adopt all the amendments in the same period. The Company elected to early adopt ASU 2019-12 effective January 1, 2020 on a prospective basis. As a result of this election, no benefit from income tax was recorded in continuing operations and no tax provision was recorded in other comprehensive income for the year ended December 31, 2020 related to the Company's loss from continuing operations and unrealized gain on available-for-sale securities during the same period. Further, the Company's adoption had no impact to its effective tax rate.

On January 1, 2020, the Company adopted ASU 2016-13: Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The guidance modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. As a result of adoption, the Company presents these financial assets, which includes its available-for-sale debt securities, at the net amount it expects to collect. The amendment also requires that the Company records credit losses related to its available-for-sale debt securities as an allowance through net income rather than reducing the carrying amount under the historical, other-than-temporary-impairment model. The Company's adoption of ASU 2016-13 did not materially affect the Financial Statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

The Company has reviewed other recently issued accounting pronouncements and concluded they are either not applicable to the business or that no material effect is expected on the Financial Statements as a result of future adoption.

Impact of Recent Legislation

In March 2020, the Coronavirus Aid, Relief and Economic Security Act ("the CARES Act") was signed into law. The CARES Act includes provisions relating to several aspects of corporate income taxes. The Company does not currently expect the CARES Act to have a material impact on its income tax positions; however, it will continue to monitor the provisions of the CARES Act in relation to its operations.

3. Fair Value Measurements

The Company measures and reports certain financial instruments as assets and liabilities at fair value on a recurring basis. The Company's financial assets measured at fair value on a recurring basis were as follows (in thousands):

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 205,408	$ —	$ —	$ 205,408
Total cash equivalents	205,408	—	—	205,408
Short-term marketable securities				
U.S. treasuries	451,820	—	—	451,820
Total short-term marketable securities	451,820	—	—	451,820
Total cash equivalents and short-term marketable securities	$ 657,228	$ —	$ —	$ 657,228

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 35,935	$ —	$ —	$ 35,935
Total cash equivalents	35,935	—	—	35,935
Short-term marketable securities				
U.S. treasuries	457,534	—	—	457,534
Total short-term marketable securities	457,534	—	—	457,534
Total cash equivalents and short-term marketable securities	$ 493,469	$ —	$ —	$ 493,469

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between levels during the years ended December 31, 2020 and 2019.

4. Marketable Securities

All marketable securities were considered available-for-sale at December 31, 2020 and 2019. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's marketable securities by major security type are summarized in the table below (in thousands):

	December 31, 2020			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale securities				
U.S. treasuries classified as investments	$ 451,812	$ 26	$ (18)	$ 451,820
Total	$ 451,812	$ 26	$ (18)	$ 451,820

	December 31, 2019			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale securities				
U.S. treasuries classified as investments	$ 457,397	$ 161	$ (24)	$ 457,534
Total	$ 457,397	$ 161	$ (24)	$ 457,534

The amortized cost of available-for-sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. As of December 31, 2020 and 2019, the aggregate fair value of securities held by the Company in an unrealized loss position for less than twelve months was $91.4 million and $187.4 million, respectively. All of these securities had remaining maturities of less than one year. The Company has the intent and ability to hold such securities until recovery and has determined that there has been no material change to their credit risk. As a result, the Company determined it did not hold any investments with a credit loss at December 31, 2020 and 2019.

There were no material realized gains or losses recognized on the sale or maturity of available-for-sale securities during the years ended December 31, 2020, 2019 and 2018, and as a result, there were no material reclassifications out of accumulated other comprehensive gain (loss) for the same periods.

5. Balance Sheet Components and Supplemental Disclosures

Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	December 31,	
	2020	2019
Laboratory equipment	$ 4,236	$ 4,170
Furniture and office equipment	1,784	1,695
Leasehold improvements	4,581	4,581
Construction-in-progress	1,325	—
	11,926	10,446
Less accumulated depreciation	(3,581)	(2,036)
Property and equipment, net	$ 8,345	$ 8,410

Depreciation and amortization expense for the years ended December 31, 2020, 2019 and 2018 was $1.5 million, $1.5 million and $0.2 million, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2020	2019
Accrued contract research and development expense	$ 4,697	$ 4,990
Accrued compensation and benefits expense	3,214	1,608
Current portion of operating lease liabilities	492	410
Other current liabilities	87	90
Total	$ 8,490	$ 7,098

6. Commitments and Contingencies

Operating Leases

The Company's lease obligations primarily relate to leased office and laboratory space under noncancelable operating leases. In accordance with ASC 842, the Company has performed an evaluation of its other contracts with vendors and has determined that, except for the leases described below, none of its other contracts contain a lease.

2018 Redwood City Lease

In January 2018, the Company entered into an operating lease agreement for approximately 25,000 square feet of office and laboratory space in Redwood City, California (the "2018 Redwood City Lease"). The contractual term of the 2018 Redwood City Lease is 10.75 years beginning from the substantial completion and delivery of the premises, which occurred in November 2018, and terminating in July 2029. The 2018 Redwood City Lease provides rent abatements and includes a one-time option to extend the lease term for five years. This option to extend the lease term was not determined to be reasonably certain and therefore has not been included in the Company's calculation of the associated operating lease liability under ASC 842.

The 2018 Redwood City Lease includes monthly base rent amounts escalating over the term of the lease. In addition, the lessor provided for a tenant improvement allowance ("TIA") up to $1.4 million, which was fully utilized. The TIA was recorded as leasehold improvements, with offsetting adjustments recorded to the associated operating lease right of use asset included on the balance sheets as of December 31, 2020 and 2019.

The Company utilized its incremental borrowing rate to calculate the present value of the lease payments for the 2018 Redwood City Lease based on information available on January 1, 2019, the adoption date of ASC 842.

2019 San Carlos Lease

In December 2019, the Company entered into an additional operating lease agreement for approximately 98,000 square feet of office and laboratory space in San Carlos, California (the "2019 San Carlos Lease"). The contractual term of the 2019 San Carlos Lease is 10.25 years beginning from the substantial completion and delivery of the premises, which is expected to occur in July 2021 and terminate in September 2031. The 2019 San Carlos Lease provides rent abatements and includes a one-time option to extend the lease term for five years. This option to extend the lease term was not determined to be reasonably certain and therefore has not been included in the Company's calculation of the associated operating lease liability under ASC 842.

The 2019 San Carlos Lease includes monthly base rent amounts escalating over the term of the lease. In addition, the lessor provided for a TIA up to $14.7 million, which is expected to be fully utilized. Costs incurred during the year ended December 31, 2020 were recorded to construction-in-progress, with an offsetting adjustment recorded to the associated operating lease right of use asset included on the balance sheet as of December 31, 2020. The 2019 San Carlos Lease was not reflected on the balance sheet as of December 31, 2019 as the Company had not yet obtained control over the premises.

The Company utilized its incremental borrowing rate to calculate the present value of the lease payments for the 2019 San Carlos Lease based on information available on November 1, 2020, the lease commencement date for accounting purposes, which was the date the Company was deemed to have obtained control of the premises. Calculation of the operating lease liability also included estimated future TIA reimbursements that had not yet been received as of the lease commencement date. TIA reimbursements received subsequent to lease commencement date are recorded as reductions to the operating lease liability.

Classification of Operating Leases

The 2018 Redwood City Lease and the 2019 San Carlos Lease required security deposits of $0.8 million and $1.5 million, respectively, which the Company satisfied by establishing letters of credit secured by restricted cash. Restricted cash related to the Company's lease agreements are recorded in other long-term assets on the Company's balance sheets.

Classification of the Company's operating lease liabilities included in the Company's balance sheets at December 31, 2020 and 2019 was as follows (in thousands):

	December 31,	
	2020	2019
Operating lease liabilities		
Current portion included in accrued expenses and other current liabilities	$ 492	$ 410
Operating lease liabilities, net of current portion	42,773	8,112
Total operating lease liabilities	$ 43,265	$ 8,522

The components of lease costs, which are included in operating expenses in the Company's statements of operations and comprehensive loss were as follows (in thousands):

	Year ended December 31,	
	2020	2019
Operating lease costs	$ 2,087	$ 1,118
Variable costs	364	346
Total lease costs	$ 2,451	$ 1,464

Variable costs included in the table above represent amounts the Company pays related to property taxes, insurance, maintenance and repair costs.

Lease expense was $2.1 million, $1.1 million and $1.0 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Net cash paid for the amounts included in the measurement of the Company's operating lease liabilities and presented within cash used in operating activities in the statements of cash flows was $1.0 million and $0.4 million for the years ended December 31, 2020 and 2019, respectively.

Operating Lease Obligations

Future lease payments required under operating leases included on the Company's balance sheet at December 31, 2020 are as follows (in thousands):

Fiscal Year Ending December 31,		
2021	$	2,399
2022		8,181
2023		8,427
2024		8,679
2025		8,940
Thereafter		53,246
Total future lease payments		89,872
Less:		
Present value adjustment		32,384
Present value of future lease incentives		14,223
Operating lease liabilities	$	43,265

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company used its incremental borrowing rate based on the information available at the lease commencement date. As of December 31, 2020, the weighted-average remaining lease term of the Company's leases was 10.3 years and the weighted-average discount rate used to determine the operating lease liabilities included on the balance sheet was 8.8%.

As of December 31, 2020, the Company has not been party to any lease agreements containing material residual value guarantees or material restrictive covenants.

Purchase Obligations

The Company has entered into contractual agreements with various research and development organizations and suppliers in the normal course of its business. All contracts are terminable, with varying provisions regarding termination. If a contract were to be terminated, the Company would only be obligated for the products or services that the Company had received through the time of termination as well as any noncancelable minimum payments contractually agreed upon prior to the effective date of termination. In the case of terminating a clinical trial agreement with an investigational site conducting clinical activities on behalf of the Company, the Company would also be obligated to provide continued support for appropriate safety procedures through completion or termination of the associated study. As of December 31, 2020, the Company had $145.0 million of noncancelable purchase obligations under these agreements.

In-Licensing Agreements

The Company has entered into exclusive and non-exclusive, royalty bearing license agreements with third-parties for certain intellectual property. Under the terms of the license agreements, the Company is obligated to pay milestone payments upon the achievement of specified clinical, regulatory and commercial milestones. Research and development expense associated with the Company's milestone payments are recognized when such milestone has been achieved. Actual amounts due under the license agreements will vary depending on factors including, but not limited to, the number of products developed and the Company's ability to further develop and commercialize the licensed products. The Company is also subject to future royalty payments based on sales of the licensed products. In-licensing payments to third-parties for milestones are recognized as research and development expense in the period of achievement.

The Company recognized $3.4 million of milestone expense for the year ended December 31, 2020 related to development milestones associated with the first patient dosed in the Company's Phase 3 study with lirentelimab. No milestone expense was incurred for the year ended December 31, 2019. The Company recognized $0.3 million in milestone expense for the year ended December 31, 2018 related to development milestones associated with the first patient dosed in the Company's Phase 2 study with lirentelimab. Milestone payments are not creditable against royalties. As of December 31, 2020, the Company has not incurred any royalty liabilities related to its license agreements, as product sales have not yet commenced.

Exclusive License Agreement with The Johns Hopkins University

In December 2013, the Company entered into a license agreement with The Johns Hopkins University ("JHU") for a worldwide exclusive license to develop, use, manufacture and commercialize covered product candidates including lirentelimab, which was amended in September 30, 2016. Under the terms of the agreement, the Company has made upfront and milestone payments of $0.7 million through December 31, 2020 and may be required to make aggregate additional milestone payments of up to $3.6 million. The Company also issued 88,887 shares of common stock as consideration under the JHU license agreement. In addition to milestone payments, the Company is also subject to single-digit royalties to JHU based on future net sales of each licensed therapeutic product candidate by the Company and its affiliates and sublicensees, with up to a low six-digit dollar minimum annual royalty payment.

Non-exclusive License Agreement with BioWa Inc. and Lonza Sales AG

In October 2013, the Company entered into a tripartite agreement with BioWa Inc. ("BioWa"), and Lonza Sales AG ("Lonza"), for the non-exclusive worldwide license to develop and commercialize product candidates including lirentelimab that are manufactured using a technology jointly developed and owned by BioWa and Lonza. Under the terms of the agreement, the Company has made milestone payments of $3.4 million through December 31, 2020 and may be required to make aggregate additional milestone payments of up to $38.0 million. In addition to milestone payments, the Company is also subject to minimum annual commercial license fees of $40,000 per year to BioWa until such time as BioWa receives royalty payments, as well as low single-digit royalties to BioWa and to Lonza. Royalties are based on future net sales by the Company and its affiliates and sublicensees and vary dependent on Lonza's participation as sole manufacturer for commercial production.

Indemnification Agreements

The Company has entered into indemnification agreements with certain directors and officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, no such matters have arisen and the Company does not believe that the outcome of any claims under indemnification arrangements will have a material adverse effect on its financial positions, results of operations or cash flows. Accordingly, the Company has not recorded a liability related to such indemnifications at December 31, 2020.

Legal Contingencies

On March 10, 2020, a putative securities class action complaint captioned Kim v. Allakos et al., No. 20-cv-01720 (N.D. Cal.) was filed in the United States District Court for the Northern District of California against the Company, its Chief Executive Officer, Dr. Robert Alexander, and its former Chief Financial Officer, Mr. Leo Redmond. The complaint asserts claims for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder and seeks damages based on alleged material misrepresentations and omissions concerning its Phase 2 clinical trials of lirentelimab. The proposed class period is August 5, 2019, through December 17, 2019, inclusive. On August 28, 2020, the plaintiff filed an amended complaint, adding as defendants Dr. Adam Tomasi, the Company's President, Chief Operating Officer and Chief Financial Officer, and Dr. Henrik Rasmussen, the Company's Chief Medical Officer. Given the early stage of this litigation matter, the Company cannot reasonably estimate a potential future loss or a range of potential future losses and has not recorded a contingent liability accrual as of December 31, 2020.

7. Stockholders' Equity

The Company's amended and restated certificate of incorporation filed on July 23, 2018 authorizes the issuance of a total of 220,000,000 shares of stock. Of these shares, 200,000,000 are designated as common stock and 20,000,000 are designated as preferred stock.

Common Stock

There were 53,080,538 shares of common stock issued and outstanding at December 31, 2020. Common shares reserved for future issuance upon the exercise, issuance or conversion of the respective equity instruments are as follows (in thousands):

	December 31,	
	2020	2019
Exercise of common stock options outstanding	6,616	7,148
Shares reserved for issuance under equity incentive plans	5,271	3,762
Vesting of restricted stock units	1,161	542
Shares reserved for issuance under employee stock purchase plans	1,265	848
Total	14,313	12,300

Common stockholders are entitled to dividends if and when declared by the Board of Directors subject to the prior rights of preferred stockholders. As of December 31, 2020, no dividends on common stock had been declared by the Board of Directors.

Preferred Stock

There were no shares of preferred stock issued and outstanding at December 31, 2020.

8. Stock-Based Compensation

Total stock-based compensation expense recognized is as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Research and development	$ 11,583	$ 5,351	$ 1,792
General and administrative	21,863	10,413	2,778
Total	$ 33,446	$ 15,764	$ 4,570

No income tax benefits for stock-based compensation expense have been recognized for the years ended December 31, 2020, 2019 and 2018 as a result of the Company's full valuation allowance applied to net deferred tax assets and net operating loss carryforwards.

Equity Incentive Plans

In July 2018, the Board of Directors adopted the 2018 Equity Incentive Plan (the "2018 Plan"). The 2018 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units ("RSUs"), stock appreciation rights and other stock-based awards. The Company initially reserved 4,000,000 shares of common stock for issuance under the 2018 Plan. The number of shares of common stock that may be issued under the 2018 Plan will automatically increase on each January 1, beginning with the fiscal year ending December 31, 2019, equal to the least of (i) 5,000,000 shares, (ii) 5% of the outstanding shares of common stock as of the last day of the preceding fiscal year and (iii) such other amount as the Board of Directors may determine. Stock options and RSUs granted under the 2018 Plan generally vest over four years and expire no more than 10 years from the date of grant.

Following the IPO and upon the effectiveness of the 2018 Plan, the Company's 2012 Equity Incentive Plan, as amended, (the "2012 Plan"), terminated and no further awards will be granted thereunder. All outstanding awards under the 2012 Plan will continue to be governed by their existing terms. Any shares subject to awards granted

under the 2012 Plan that, on or after the termination of the 2012 Plan, expire or terminate and shares previously issued pursuant to awards granted under the 2012 Plan that, on or after the termination of the 2012 Plan, are forfeited or repurchased by the Company will be transferred into the 2018 Plan. As of December 31, 2020, the maximum number of shares that may be added to the 2018 Plan pursuant to the preceding clause is 4,668,032 shares.

Prior to its termination, the 2012 Plan provided for the grant of stock options, stock appreciation rights, restricted stock and restricted stock units to employees, directors and consultants. Stock options granted under the 2012 Plan generally vest over four years and expire no more than 10 years from the date of grant.

Stock Options

Stock option activity under the 2018 Plan and the 2012 Plan is summarized as follows (in thousands, except per share data):

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Years	Aggregate Intrinsic Value
Balance at December 31, 2019	7,148	$ 12.96	8.0	$ 589,114
Granted	195	$ 83.64		
Exercised	(700)	$ 8.15		
Forfeited	(27)	$ 19.08		
Balance at December 31, 2020	6,616	$ 15.53	7.1	$ 823,532
Options exercisable	4,746	$ 9.03	6.8	$ 621,539
Options vested and expected to vest	6,604	$ 15.48	7.1	$ 822,365

The following weighted-average assumptions were used to calculate the fair value of stock options granted during the periods indicated:

	Year Ended December 31,		
	2020	2019	2018
Risk-free interest rate	0.50%	1.91%	2.79%
Expected volatility	70.78%	67.22%	73.47%
Expected dividend yield	—	—	—
Expected term (in years)	5.95	6.01	6.01

The weighted-average fair value of options granted during the years ended December 31, 2020, 2019 and 2018 was $51.59, $28.66 and $11.05 per share, respectively.

The aggregate fair value of stock options that vested during the years ended December 31, 2020, 2019 and 2018 was $18.0 million, $12.6 million and $1.8 million, respectively.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. Following the IPO, the aggregate intrinsic value represents the value of the Company's closing stock price on the last trading day of the year in excess of the weighted-average exercise price multiplied by the number of options outstanding or exercisable. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2020, 2019 and 2018 was $62.2 million, $55.8 million and $ 2.0 million, respectively.

During the years ended December 31, 2020, 2019 and 2018, the Company did not grant any stock options with performance-based or market-based vesting conditions.

As of December 31, 2020, total unrecognized stock-based compensation expense relating to unvested stock options was $33.9 million. This amount is expected to be recognized over a weighted-average period of 2.4 years.

Restricted Stock Awards

The 2012 Plan allows for the issuance of restricted common stock and early exercise of unvested stock options in exchange for restricted common stock. Unvested shares of restricted common stock are subject to repurchase by the Company at the original issuance price in the event of the employee's termination, either voluntarily or involuntarily. Consideration received for unvested stock-based awards is initially recorded as a liability and subsequently reclassified into stockholders' deficit as the related awards vest.

There were no unvested shares of restricted common stock at December 31, 2020 and 2019. The fair value of restricted common stock that vested during the years ended December 31, 2020, 2019 and 2018 was $0, $20,000 and $24,000, respectively.

Restricted Stock Units

RSU activity under the 2018 Plan is summarized as follows (in thousands, except per share data):

	Number of Shares		Weighted-Average Grant Date Fair Value
Balance at December 31, 2019	542	$	93.67
Granted	762	$	106.56
Vested	(137)	$	93.32
Forfeited	(6)	$	81.85
Balance at December 31, 2020	1,161	$	102.24

The weighted-average fair value of RSUs granted during the year ended December 31, 2020, 2019 and 2018 was $106.56, $93.67,and $0, respectively.

As of December 31, 2020, total unrecognized stock-based compensation expense relating to unvested RSUs was $113.6 million and the weighted-average remaining vesting period was 3.6 years.

The aggregate intrinsic value of RSUs is calculated as the closing price per share of the Company's common stock on the last trading day of the fiscal period, multiplied by the number of RSUs expected to vest as of December 31, 2020. As of December 31, 2020, the aggregate intrinsic value of RSUs was $162.5 million.

Employee Stock Purchase Plan

In July 2018, the Company's Board of Directors and stockholders approved the 2018 Employee Stock Purchase Plan (the "2018 ESPP"). There were 500,000 shares of common stock initially reserved for issuance under the 2018 ESPP. The number of shares of common stock that may be issued under the 2018 ESPP shall automatically increase on each January 1, beginning with the fiscal year ending December 31, 2019, equal to the least of (i) 1,000,000 shares, (ii) 1% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year and (iii) such other amount determined by the 2018 ESPP administrator. Under the 2018 ESPP, employees may purchase shares of the Company's common stock at a price per share equal to 85% of the lower of the fair market value of the common stock on the first trading day of the offering period or on the exercise date. The 2018 ESPP provides for consecutive, overlapping 24-month offering periods, each of which will include purchase periods. The first offering period commenced on July 18, 2018.

During the year ended December 31, 2020, 2019 and 2018, stock-based compensation related to the 2018 ESPP was $0.9 million, $0.7 million and $0.2 million, respectively.

The following weighted-average assumptions were used to calculate the fair value of ESPP shares during the periods indicated:

	Year Ended December 31,		
	2020	2019	2018
Risk-free interest rate	0.58%	2.37%	2.42%
Expected volatility	61.80%	64.26%	65.29%
Expected dividend yield	—	—	—
Expected term (in years)	1.20	1.22	1.24

As of December 31, 2020, total unrecognized compensation expense relating to shares to be purchased under the 2018 ESPP was $1.1 million over a weighted-average period of 1.4 years.

9. Income Taxes

The Company's deferred income tax assets include operating losses and tax credit carryforwards, as well as certain temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Total deferred income tax assets, net of valuation allowance, at December 31, 2020 and 2019 were as follows (in thousands):

	December 31,	
	2020	2019
Deferred tax assets		
Net operating loss carryforwards	$ 87,124	$ 47,003
Research and development credits	18,139	8,644
Accruals and reserves	1,368	1,199
Stock-based compensation	5,661	2,870
Lease liability	9,151	1,798
Gross deferred tax assets	121,443	61,514
Less: valuation allowance	(112,680)	(59,901)
Deferred tax assets, net of valuation allowance	8,763	1,613
Deferred tax liabilities		
Fixed and intangible assets	360	395
Right-of-use asset	8,403	1,218
Gross deferred tax liabilities	8,763	1,613
Net deferred tax assets	$ —	$ —

Management has evaluated the positive and negative evidence surrounding the realizability of its deferred tax assets and has determined that it is more likely than not that the Company will not recognize the benefits of its federal and state deferred tax assets, and as a result, a valuation allowance of $112.7 million and $59.9 million has been established at December 31, 2020 and 2019, respectively. The change in the valuation allowance was $52.8 million and $31.0 million for the years ended December 31, 2020 and 2019, respectively. The Company has incurred net operating losses ("NOL") since inception. As of December 31, 2020, the Company had federal and state NOL carryforwards of $399.9 million and $48.1 million, respectively. Federal NOL carryforwards of $338.0 million, which were generated after December 31, 2017, do not expire. The remaining $61.9 million of Federal NOL carryforwards expire beginning in 2032. As of December 31, 2020, the Company had federal and California research and other tax credit carryforwards of $20.3 million and $5.6 million, respectively. The federal tax credits expire beginning in 2033. The California tax credits can be carried forward indefinitely.

The Internal Revenue Code of 1986, as amended (the "Code"), provides for a limitation of the annual use of net operating losses and other tax attributes (such as research and development tax credit carryforwards) following certain ownership changes defined by the Code that could limit the Company's ability to utilize these carryforwards in the future. At this time, the Company has not completed a study to assess whether an ownership change under Section 382 of the Code has occurred, or whether there have been multiple ownership changes since the Company's

formation. The Company may have experienced ownership changes, as defined by the Code, as a result of past financing transactions and may not be able to take full advantage of these carryforwards for federal or state income tax purposes.

The effective tax rate for the years ended December 31, 2020 and 2019 is different from the federal statutory rate primarily due to the valuation allowance against deferred tax assets as a result of insufficient income. The Company's effective tax rate differs from the federal statutory tax rate as follows:

	Year Ended December 31,	
	2020	2019
Federal statutory tax rate	21.0%	21.0%
Change in deferred tax asset valuation allowance	(34.4)%	(36.4)%
State taxes, net of federal benefit	0.8%	1.1%
Research and development tax credits	5.6%	4.4%
Stock-based compensation	6.9%	9.9%
Other	0.1%	—%
Effective tax rate	—%	—%

Uncertain Tax Positions

The Company accounts for its uncertain tax positions in accordance with FASB ASC Topic No. 740-10, *Accounting for Uncertainty in Income Taxes* ("ASC 740-10"). Per ASC 740-10, the Company determines its uncertain tax positions based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings is more likely than not to be sustained upon examination by the relevant income tax authorities.

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

	Year Ended December 31,	
	2020	2019
Balance at the beginning of the year	$ 3,545	$ 1,827
Increase related to current year tax positions	3,387	1,718
Balance at the end of the year	$ 6,932	$ 3,545

The entire amount of the unrecognized tax benefits would not impact the Company's effective tax rate if recognized. During the years ended December 31, 2020 and 2019, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease during the next twelve months.

The Company files income tax returns in the U.S. federal and multiple state tax jurisdictions. The federal and state income tax returns from inception to December 31, 2020 remain subject to examination.

During the third quarter of 2020, the U.S. Internal Revenue Service ("IRS") commenced an examination of the Company's federal corporate income tax return for the year ended December 31, 2018. The Company believes that it has adequately provided for any adjustments that may result from the IRS examination, however, the outcome of tax examinations cannot be predicted with certainty. The examination was not yet completed as of December 31, 2020.

It is the Company's policy to include penalties and interest expense related to income taxes as a component of the income tax provision as necessary. Management determined that no accrual for interest and penalties was required at December 31, 2020 and 2019. Since the Company is in a loss carryforward position, it is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available.

Recent Changes to U.S. Tax Law

In December 2017, the 2017 Tax Cuts and Jobs Act (the "2017 Tax Act") was enacted and includes a broad range of provisions, many of which differ significantly from those contained in previous U.S. tax law. The Company accounts for changes in tax law in accordance with ASC 740 which requires companies to recognize the effect of such changes in the period of enactment. However, the SEC staff issued Staff Accounting Bulletin 118 which will allow companies to record provisional amounts during a measurement period that is similar to the measurement period used when accounting for business combinations. Accordingly, the Company adjusted its deferred taxes and related valuation allowances on a provisional basis to reflect the reduction in U.S. federal corporate tax rate from 35% to 21%, based on current understanding of the new law. As of December 31, 2018, the Company has completed its analysis of the income effects of the 2017 Tax Act. There was no material impact on the Company's financial statements as a result of the analysis.

10. Defined Contribution Plans

In January 2018, the Company established a defined contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) plan"). The 401(k) plan covers all employees who meet defined minimum age and service requirements. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under U.S. federal tax regulations. The Company makes matching contributions of up to 4% of the eligible employees' compensation to the 401(k) plan. During the years ended December 31, 2020, 2019 and 2018, the Company made contributions to the 401(k) plan of $0.7 million, $0.5 million and $0.3 million, respectively.

11. Selected Quarterly Financial Data (Unaudited)

The following tables summarize the Company's quarterly results for the years ended December 31, 2020 and 2019 (in thousands, except per share data):

	Quarter Ended			
	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020
Loss from operations	$ (29,873)	$ (40,404)	$ (42,435)	$ (44,345)
Net loss	$ (27,824)	$ (39,292)	$ (42,086)	$ (44,278)
Net loss per common share, basic and diluted	$ (0.57)	$ (0.80)	$ (0.86)	$ (0.86)

	Quarter Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Loss from operations	$ (20,927)	$ (20,057)	$ (23,584)	$ (26,850)
Net loss	$ (19,953)	$ (19,072)	$ (21,732)	$ (24,615)
Net loss per common share, basic and diluted	$ (0.47)	$ (0.44)	$ (0.47)	$ (0.51)

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

Our management, with the participation of our Chief Executive Officer and our President, Chief Operating Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. 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 management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, our Chief Executive Officer and President, Chief Operating Officer and Chief Financial Officer concluded that the design and operation of our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2020.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the *Internal Control–Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal controls over financial reporting were effective as of December 31, 2020.

The effectiveness of our internal control over financial reporting as of December 31, 2020 has also been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in its report included in this Annual Report on Form 10-K.

Inherent Limitations on the Effectiveness of Internal Control

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.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fourth quarter of the year ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Allakos Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Allakos Inc. ‘s internal control over financial reporting as of December 31, 2020, 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, Allakos Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, 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 balance sheets of the Company as of December 31, 2020 and 2019, the related statements of operations and comprehensive loss, statements of convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and our report dated February 26, 2021 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 Annual 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

Redwood City, California
March 1, 2021

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to regulation 14A, or the Proxy Statement, which proxy statement is expected to be filed with Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2020.

Item 11. Executive Compensation.

The information required by this item will be set forth in the Proxy Statement 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 will be set forth in the Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in the Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

See Index to Financial Statements included in Part II Item 8 of this Annual Report on Form 10-K

(2) Financial Statement Schedules

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

(3) List of Exhibits required by Item 601 of Regulation S-K

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Number	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-38582	3.1	7/24/2018	
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-38582	3.2	7/24/2018	
4.1	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated November 30, 2017.	S-1/A	333-225836	4.1	6/22/2018	
4.2	Specimen common stock certificate of the Registrant.	S-1/A	333-225836	4.2	7/09/2018	
10.1+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-225836	10.1+	6/22/2018	
10.2+	2012 Equity Incentive Plan, as amended, and forms of agreement thereunder.	S-1	333-225836	10.2+	6/22/2018	
10.3+	2018 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	333-225836	10.3+	7/09/2018	
10.4+	2018 Employee Stock Purchase Plan.	S-1/A	333-225836	10.4	7/09/2018	
10.5+	Employment Letter between the Registrant and Robert Alexander, Ph.D.	S-1/A	333-225836	10.5+	7/09/2018	
10.6+	Employment Letter between the Registrant and Adam Tomasi, Ph.D.	S-1/A	333-225836	10.6+	7/09/2018	
10.7+	Employment Letter between the Registrant and Henrik Rasmussen, M.D., Ph.D.	S-1/A	333-225836	10.7+	7/09/2018	
10.8+	Employment Letter between the Registrant and Leo Redmond	10-Q		10.8+	8/05/2019	
10.9+	Separation Agreement between the Registrant and Leo Redmond	8-K		10.1	12/11/2020	
10.10+	Executive Incentive Compensation Plan.	S-1	333-225836	10.9+	6/22/2018	
10.11+	Outside Director Compensation Policy.	S-1/A	333-225836	10.10+	7/09/2018	
10.12+	Amended and Restated Outside Director Compensation Policy.	10-Q		10.2+	5/11/2020	
10.13+	Change in Control and Severance Policy.	S-1/A	333-225836	10.11+	7/09/2018	

10.14	Lease Agreement between the Registrant and Westport Office Park, LLC, dated January 4, 2018, as amended.	S-1	333-225836	10.12	6/22/2018	
10.15	Lease Agreement between the Registrant and ARE-San Francisco No. 63, LLC, dated December 4, 2019.	10-K		10.13	2/25/2020	
10.16#	Non-exclusive License Agreement between the Registrant, BioWa, Inc. and Lonza Sales AG, dated October 31, 2013.	S-1/A	333-225836	10.14#	7/17/2018	
10.17#	Amended and Restated Exclusive License Agreement between the Registrant and the Johns Hopkins University, dated September 30, 2016.	S-1/A	333-225836	10.15#	7/17/2018	
10.18#	Commercial Supply Agreement between the Registrant and Lonza Sales AG, dated April 7, 2020.	10-Q		10.1#	5/11/2020	
10.19#	Commercial Supply Agreement between the Registrant and Lonza Sales AG, dated December 18, 2020.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					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					
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 Inline XBRL)	X

* Furnished herewith.

\+ Indicated management contract or compensatory plan.

\# Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

ALLAKOS INC.

Date: March 1, 2021 By: /s/ Robert Alexander

Robert Alexander, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

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

Name	Title	Date
/s/ Robert Alexander **Robert Alexander, Ph.D.**	Chief Executive Officer and Director *(Principal Executive Officer)*	March 1, 2021
/s/ Adam Tomasi **Adam Tomasi, Ph.D.**	President, Chief Operating Officer and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 1, 2021
/s/ Daniel Janney **Daniel Janney**	Chair of the Board	March 1, 2021
/s/ Robert Andreatta **Robert Andreatta**	Director	March 1, 2021
/s/ Natalie Holles **Natalie Holles**	Director	March 1, 2021
/s/ Steve James **Steve James**	Director	March 1, 2021
/s/ John McKearn **John McKearn, Ph.D.**	Director	March 1, 2021
/s/ Paul Walker **Paul Walker**	Director	March 1, 2021

Exhibit 10.19

*******Certain identified information has been omitted from this exhibit because it is both not material and would be competitively harmful if publicly disclosed.***

[Redacted] Commercial Supply Agreement

(the “Agreement”)

by and between

Lonza AG
Münchensteinerstrasse 38
CH-4002 Basel
Switzerland

- hereinafter “Lonza” -

and

Allakos, Inc.
975 Island Drive, Suite 201
Redwood City, CA 94065
USA

- hereinafter “Customer” -

Effective as of 27 November 2020 (the “Effective Date”)

Table of Contents

Recitals

WHEREAS, Customer is engaged in the development, research and sale of certain products and requires assistance in the manufacture of Product;

WHEREAS, Lonza and its Affiliates have expertise in the manufacture of products;

WHEREAS, Lonza and Customer previously entered into that certain BLA Services and Manufacturing Services Agreement dated 1st December 2017 (the "BLA Agreement") and the 2K Development Agreement (as defined below) to provide services related to Customer's AK002 Product;

WHEREAS, Customer wishes to engage Lonza for Services relating to the manufacture of the Product as described in this Agreement; and

WHEREAS, Lonza, and/or its Affiliate, is prepared to perform such Services for Customer on the terms and subject to the conditions set out herein.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the Parties intending to be legally bound, agree as follows:

1 Definitions and Interpretations

1.1 Definitions.

"1K Commercial Supply Agreement"	means the 1K Commercial Supply Agreement dated [Redacted] between Customer and Lonza Sales AG, Lonza's Affiliate.
"[Redacted] Development Agreement"	means, collectively, [Redacted] Development and Manufacturing Services Agreement entered into between Lonza and Customer [Redacted] and any successor agreement thereof.
"Affiliate"	means any company, partnership and/or other entity which directly and/or indirectly Controls, is Controlled by and/or is under common Control with the relevant Party. "Control" means the ownership of more than fifty percent (50%) of the issued share capital and/or the legal power to direct and/or cause the direction of the general management and policies of the relevant Party.
"Agreement"	means this agreement incorporating all Appendices, as amended from time to time by written agreement of the Parties.
"Alternate Manufacturer"	means (i) Customer and each of its Affiliates or (ii) any Third Party that, [Redacted]
"Applicable Laws"	means all relevant United States, United Kingdom and European Union federal, state and local laws, statutes, rules, and regulations which are applicable to a Party's activities hereunder,

	including the applicable regulations and guidelines of any Governmental Authority and in respect of the manufacture of cGMP Batches all applicable cGMP together with amendments thereto.
“Approval”	means a marketing approval granted by a Regulatory Authority of Product.
“Approved Territory”	means [Redacted].
“Average Target Yield”	means the expected and targeted Yield for the Process at the Facility [Redacted].
“Background Intellectual Property”	means any Intellectual Property either: (i) owned and/or controlled by a Party prior to the Effective Date; and/or (ii) developed and/or acquired by a Party independently from the performance of the Services hereunder, and, in the case of Lonza, without use and/or reliance on Customer Materials and/or Customer Information, during the Term of this Agreement. Lonza’s Background Intellectual Property includes the Lonza Patent Rights and Lonza Information.
“Batch”	means the total Product obtained from one fermentation and associated purification using the Process [Redacted].
“Batch Price”	means the Price which is payable in respect of Services with respect to a Batch, which includes preparation, manufacture, quality control, analysis and release and storage, excluding only the Raw Materials, Raw Materials Fee, Cell Bank Storage fees and additional storage fees pursuant to Clause 7.3.
“Binding Order”	means the binding commitment of both Parties in relation to the Batches and/or Services made in accordance with Clause 6.1 and/or 6.2.
“BLA”	means a Biologics License Application and amendments thereto for the Product filed pursuant to the requirements of the FDA, as defined in 21 C.F.R. § 600 et seq., for FDA approval of the Product, and any corresponding non-U.S. marketing authorization application, registration and/or certification, necessary to market the Product in any country outside the United States.
“BLA Agreement”	has the meaning set forth in the Recitals.
“Campaign”	means a series of cGMP Batches at the Facility.

“Cancellation Fee”	has the meaning given in Clause 6.4.
“Cell Bank”	means Customer’s cell bank and/or cell stock of a rodent or human cell line in accordance with the Master Batch Record.
“Cell Bank Storage”	means the storage of Customer’s Cell Bank in accordance with Clause 2.8.
“Cell Line”	means the cell line known as [Redacted].
“Certificate of Analysis”	means a document prepared by Lonza listing tests performed by Lonza and/or approved External Laboratories pertaining to the cGMP Batch meeting the Specifications and associated test results.
“Certificate of Compliance”	means a document prepared by Lonza: (i) listing the manufacturing date, unique Batch number and concentration of Product in such Batch; and (ii) certifying that such Batch was manufactured in accordance with the Master Batch Record and cGMP, if applicable.
“cGMP”	means those laws and regulations applicable in the United States, United Kingdom and European Union, relating to the manufacture of medicinal products for human use, including current good manufacturing practices as specified in the ICH guidelines, including ICH Q7A “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients”, ICH Q10 “Pharmaceuticals Quality System”, US Federal Food Drug and Cosmetic Act at 21CFR (Chapters 210, 211, 600 and 610) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC. For the avoidance of doubt, Lonza’s operational quality standards are defined in internal cGMP policy documents.
“cGMP Batches”	means any Batches which are required under the applicable Binding Order to be manufactured in accordance with cGMP.
“Commencement Date”	means the date of removal of the vial of cells from frozen storage for the production of a cGMP Batch.
“Confidential Information”	means Customer Information and Lonza Information, as the context requires.
“Customer Indemnitees”	has the meaning given in Clause 11.1.

“Customer Information”	means all technical and other information that is proprietary to Customer and/or any Affiliate of Customer and that is maintained in confidence by Customer and/or any Affiliate of Customer and that is, from time to time supplied to Lonza including any materials supplied by Customer to Lonza in accordance with the Master Batch Record.
“Customer Materials”	means any components of Product, and/or other materials of any nature provided by Customer.
“Disclosing Party”	has the meaning given in Clause 12.1.
“Dispute”	has the meaning given in Clause 16.6.
“Effective Date”	has the meaning set forth in the Recitals.
“EMA”	means the European Medicines Agency, or any successor agency thereto.
“External Laboratories”	means any Third Party instructed by Lonza to undertake any Services which Lonza is not able to undertake itself as it does not form part of its business offering, Customer having been notified of the same as part of the Services proposal and having provided prior written consent to such Third Party and its designation as an External Laboratory.
“Facility”	means Lonza’s manufacturing facilities in Visp, Switzerland and/or such other Lonza facility as may be agreed upon by the Parties in writing.
“Failed Batch”	means any cGMP Batch that fails to conform with the Specifications and/or is not manufactured in accordance with cGMP and/or the Quality Agreement.
“FDA”	means the United States Food and Drug Administration, or any successor agency thereto.
“Force Majeure”	has the meaning given in Clause 14.2.
“Forecast”	has the meaning given in Clause 6.1.
“Governmental Authority”	means any Regulatory Authority and any national, multi-national, regional, state and/or local regulatory agency, department, bureau, and/or other governmental entity in the United States, United Kingdom and/or European Union.
“GS”	means the glutamine synthetase expression system of which Lonza is the proprietor.

“GS Licence”	means the licence granted by Lonza (and BioWa Inc.) in respect of the use of GS and Potelligent CHOK1SV under that certain Non-Exclusive License Agreement between Lonza, Customer and BioWa Inc., dated 31st October 2013.
“ICC”	has the meaning given in Clause 16.6.
“Improvements”	has the meaning given in Clause 9.7.2.
“Indemnitor”	has the meaning given in Clause 11.3.
“Initial Storage Term”	has the meaning given in Clause 2.8.1.
“Intellectual Property”	means: (i) inventions (whether or not patentable), patents, trade secrets, copyrights, trademarks, trade names and domain names, rights in designs, rights in computer software, database rights, rights in confidential information (including know-how) and any other intellectual property rights, in each case whether registered or unregistered; (ii) all applications (and/or rights to apply) for, and renewals and/or extensions of, any of the rights described in the foregoing clause (i); and (iii) all rights and applications that are similar and/or equivalent to the rights and applications described in the foregoing clauses (i) and (ii), which exist now, and/or which come to exist in the future, in any part of the world.
“Joint Steering Committee”	has the meaning given in Clause 3.3.
“Latent Defects”	has the meaning given in Clause 7.4.1.
“Lonza Indemnitees”	has the meaning given in Clause 11.2.
“Lonza Information”	means all information that is proprietary to Lonza and/or any Affiliate of Lonza and that is maintained in confidence by Lonza and/or any Affiliate of Lonza and that is disclosed by Lonza and/or any Affiliate of Lonza to Customer under and/or in connection with this Agreement, including any and all Lonza Know-How and trade secrets.
“Lonza Know-How”	means all technical and other information relating directly or indirectly to the Process and/or the performance of the Services known to Lonza and/or its Affiliates from time to time other than Customer Information and information in the public domain.
“Lonza Operating Documents”	means the corporate standards, standard operating procedures and standard manufacturing procedures, in each case, used

	by Lonza for operation and maintenance of the Facility and Lonza equipment used in the Process, which may include electronic programs and files, protocols, validation documentation, and supporting documentation, but excluding any of the foregoing that are unique or specific to the Products.
“Lonza Patent Rights”	means all patents and patent applications of any kind throughout the world relating to the Process which from time to time Lonza and/or any Affiliate of Lonza is the owner of and/or is entitled to use.
“Lonza Responsibility”	has the meaning given in Clause 7.4.4.
“Manufacturing Regulatory Delay”	means any delay in the manufacture of, and/or delay in Customer’s need for, the Product as a consequence of a Regulatory Authority finding, ruling and/or failure of Approval [Redacted].
“Master Batch Record”	means the document which defines the manufacturing methods, test methods and other procedures, directions and controls associated with the manufacture and testing of cGMP Batches.
“New Customer Intellectual Property”	has the meaning given in Clause 9.2.
“New General Application Intellectual Property”	has the meaning given in Clause 9.3.
“Party”	means each of Lonza and Customer and, together, the “Parties”.
“Price”	means the price for the Products as specified in Clause 8.1 or for other Services as set forth in an agreed upon SOW.
“Process”	means Lonza’s and its Affiliates’ platform process for the development and production of the Product from the Cell Line, including any improvements and/or modifications thereto that are owned and/or controlled by Lonza and/or any Affiliate of Lonza from time to time.
“Product”	means the proprietary molecule identified by Customer as AK002, to be manufactured using the Process as specified in the Specifications and the Master Batch Record.
“Project Plan”	means the Project Plan as attached to and defined in the 2K Development Agreement.
“Quality Agreement”	means the quality agreement entered into between the Parties [Redacted] setting out the

	responsibilities of the Parties in relation to quality as required for compliance with cGMP.
“Raw Materials”	means all ingredients, solvents and other components of the Product required to perform the Process and/or Services set forth in the bill of materials detailing the same (including Resins and membranes but excluding any consumables and/or wearables).
“Raw Materials Fee”	means the procurement and handling fee [Redacted] of the acquisition cost of Raw Materials (including Resins) by Lonza that is charged to Customer in addition to the cost of such Raw Materials.
“Receiving Party”	has the meaning given in Clause 12.1.
“Regulatory Authority”	means the FDA, EMA and any other similar regulatory authorities as may be agreed upon in writing by the Parties.
“Release”	has the meaning given in Clause 7.1.
“Resins”	means the chromatographic media to refine and/or purify the Products, as specified in the Master Batch Record and/or Specifications.
“Rules”	has the meaning given in Clause 16.6.
“Separate Agreements”	means, collectively, the BLA Agreement, 2K Development Agreement, 20K Development Agreement, and 1K Commercial Supply Agreement.
“Services”	means all or any part of the services to be performed by Lonza under this Agreement (including the manufacture of Product and as set forth in any SOW).
“SOW”	has the meaning given in Clause 6.2.
“Specifications”	means the specifications of the Product agreed between the Parties which may be amended from time to time in accordance with this Agreement.
“Storage Requirements”	means the Cell Bank storage requirements as set out in the Master Batch Record.
“Subcontractor”	means any Third Party that Lonza uses to perform any part of the Service, including as a subcontractor and/or delegate, but excluding External Laboratories.

“Supply Failure	has the meaning given in Clause 7.5.2.
“Technology Transfer Notice”	has the meaning given in Clause 9.8.2.
“Term”	has the meaning given in Clause 13.1.
“Third Party”	means any party other than Customer, Lonza and their respective Affiliates.
“Willful Breach”	means a willful refusal to perform a Party’s obligations under this Agreement, including, without limitation, if Lonza elects to provide any batch slot reserved or scheduled for Customer in the Binding Portion of any Forecast to another customer of Lonza.
“Yield”	means the amount, in kilograms, of Product actually produced from a Batch.

1.2 Interpretation. In this Agreement references to the Parties are to the Parties to this Agreement, headings are used for convenience only and do not affect its interpretation, references to a statutory provision include references to the statutory provision as modified or re-enacted or both from time to time and to any subordinate legislation made under the statutory provision, references to the singular include the plural and vice versa, references to the word “including” are to be construed without limitation, and neither Party and/or its Affiliates shall be deemed to be acting “on behalf of” and/or “under the authority of” the other Party.

2 Performance of Services

2.1 Performance. Customer hereby retains Lonza to manufacture and supply the Product and perform other Services as set forth in and in accordance with the terms and conditions of this Agreement. Subject to Clause 2, Lonza shall itself and through its Affiliates, diligently carry out the Services and use commercially reasonable efforts to perform all Services without any material defect and according to the Binding Orders, the Specifications, the Master Batch Record and/or the applicable SOW. Lonza shall ensure that all of the Services hereunder are performed at the Facility and/or at a Subcontractor’s facility which has been approved and audited by Lonza, as applicable, unless Customer has provided its prior written consent to performance thereof at an alternate location.

2.2 Personnel and Subcontractors. Lonza shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform the Services in accordance with this Agreement. Lonza may subcontract and/or delegate any of its rights and/or obligations under this Agreement to perform the Services solely with Customer’s prior written approval (such approval not to be unreasonably withheld and/or delayed), provided that such Subcontractors are appropriately and fully qualified in all respects to perform the applicable Services, that such Subcontractors are subject to obligations of confidentiality at least as stringent and as protective of Customer as those obligations of confidence and non-use imposed upon Lonza, and that such Subcontractors are subject to obligations to act diligently and in accordance with best practice in respect of cGMP manufacture as contained in this Agreement. [Redacted].

2.3 cGMP Batches. Lonza shall manufacture cGMP Batches to meet the Specification; [Redacted] Lonza will not make any changes to the Master Batch Record, Specifications, Process, Raw Materials or any other item related to the Product(s) or their manufacture without [Redacted] obtaining Customer's prior written approval.

2.4 Supply of Customer Information and Customer Materials. Customer shall supply to Lonza all Customer Information and Customer Materials and other information and/or materials that may be reasonably required by Lonza to perform the Services, in each case as identified in the Master Batch Record, and hereby grants Lonza the non-exclusive right to use the Cell Line, the Customer Materials and the Customer Information for the purpose of this Agreement. Lonza shall not be responsible for any delays arising out of Customer's failure to provide Lonza such Customer Information, Customer Materials or other information or materials as set forth in the Master Batch Record, and Customer shall be responsible for all additional costs and expenses arising out of such delay; provided that Lonza shall promptly give Customer notice if any such failure is preventing and/or delaying Lonza's performance. Lonza shall not use the Cell Line, Customer Materials and/or Customer Information (and/or any part thereof) for any purpose other than the performance of the Services under this Agreement.

2.5 Raw Materials. Lonza shall procure all required Raw Materials as well as consumables. Customer shall be responsible for payment for all consumables and Raw Materials ordered or irrevocably committed to be procured by Lonza hereunder for the manufacture of Batches pursuant to Binding Orders. If agreed by the Parties, upon advance payment by Customer, Lonza shall purchase and hold a minimum of [Redacted] to serve as safety stock, as well as [Redacted]. Upon cancellation of any Batch pursuant to a Binding Order or termination of the Agreement, all such unused Raw Materials shall be [Redacted].

2.6 Use of GS Technology. Customer acknowledges that the Cell Line uses GS and that the GS Licence applies to in vivo clinical studies and/or any other commercial use and/or sale of the Product manufactured using the Cell Line.

2.7 Known Hazards. Lonza acknowledges that it has received from Customer the Customer Information, together with full details of any hazards relating to the Cell Line and the Customer Materials, their storage and use. All property rights and Intellectual Property rights in the Cell Line and/or the Customer Materials and/or the Customer Information supplied to Lonza shall remain vested in Customer.

2.8 Cell Bank Storage.

2.8.1 Cell Bank Storage has commenced pursuant to the 2K Development Agreement, and shall continue, unless otherwise terminated in accordance with Clause 2.8.6, for [Redacted] (the "Initial Storage Term"). Lonza shall store the Cell Bank in accordance with the Storage Requirements and Lonza shall not transfer the Cell Bank to a Third Party (other than an Affiliate of Lonza) without Customer's prior written consent. Lonza reserves the right to perform testing of the Cell Bank which Lonza requires for QA, regulatory or safety purposes.

2.8.2 Cell Banks stored at Lonza shall at all times remain Customer's property (subject always to the terms of any other agreements or licenses of Customer with Lonza, and subject to any Third-Party Intellectual Property rights), save that the Cell Bank shall be subject to a lien in respect of any sums owed under any agreement by Customer to Lonza.

2.8.3 If Customer wishes to withdraw the Cell Bank from storage, it shall give Lonza [Redacted]. prior written notice. Lonza and Customer shall agree a date for the Cell Bank to be withdrawn. Customer shall be responsible for arranging (and costs of) collection and shipping. Once the Cell Bank has been withdrawn, Lonza shall have no further obligations in respect thereof (provided that the foregoing shall not affect any remedies for breach of an obligation prior to such withdrawal by Customer).

2.8.4 Notwithstanding any other provisions of this Agreement, the price of Cell Bank Storage is calculated and shall be payable on a [Redacted] basis. Payment shall be made [Redacted] prior to the anniversary of storage commencement during the Term. Customer shall not be entitled to any refund in respect of any partial use of Cell Bank Storage, unless this Agreement is terminated by Customer other than pursuant to Clause 13.2.1, in which case Lonza shall refund to Customer the unused portion of the fees paid in relation to the period after the effective date of termination. The initial price for Cell Bank Storage is set out in Appendix C hereto and shall be subject to review in accordance with Clause 8.6. If Customer does not pay for Cell Bank Storage by the due date, Lonza shall not be obliged to continue the Cell Bank Storage and Customer shall be required within [Redacted] of Lonza's written notice to arrange collection and shipping of the Cell Bank, unless Customer cures such payment default within such [Redacted] period, in which case the Cell Bank Storage shall continue. For clarity, Cell Banks stored by Lonza at the Facility may be used for activities under this Agreement, and the 2K Development Agreement, and only one fee is applicable to such stored Cell Banks.

2.8.5 Lonza shall use reasonable endeavours to protect the Cell Bank from destruction, theft and/or loss during Cell Bank Storage. Notwithstanding any other provision of this Agreement, risk of loss or damage to the Cell Bank shall remain with Customer at all times, except that Lonza shall be responsible for loss and/or damage of the Cell Bank arising from Lonza's and/or its Affiliate's and/or Subcontractor's negligence and/or intentional misconduct. Notwithstanding Clause 11.5, the total aggregate liability of Lonza and/or its Affiliates for all claims (whether in contract, tort, negligence, breach of statutory duty, under an indemnity, for any strict liability and/or otherwise) in connection with and/or arising out of Cell Bank Storage shall not exceed [Redacted] under the all of the Separate Agreements and hereunder. For clarity, the foregoing limitation of liability shall not apply with respect to any unauthorized transfer of the Cell Line to a Third Party.

2.8.6 Customer may terminate the Cell Bank Storage by [Redacted] written notice to Lonza. Customer shall not be entitled to any refunds in respect of any unused element of Cell Bank Storage except to the extent Cell Bank Storage is terminated by Lonza. Upon termination of this Agreement and/or Cell Bank Storage and upon payment of all undisputed sums due to Lonza, Customer shall either arrange for collection of the Cell Bank or instruct Lonza to destroy it, in which case Customer shall pay Lonza the costs of such destruction. Lonza may terminate the Cell Bank Storage solely upon termination of this Agreement by Lonza or as set forth in Clause 2.8.4. In the event of termination by Lonza, except when such termination by Lonza is due to non-payment of undisputed invoices by Customer, [Redacted].

3 Project Management

3.1 2K Development Agreement and Project Plan. The Parties acknowledge that certain activities and tasks are being undertaken under the Project Plan (as amended in accordance with the 2K Development Agreement) and the 2K Development Agreement on and after the Effective Date. The manufacture of Batches under the 2K Development Agreement shall be governed solely by the 2K Development Agreement and not this Agreement. Certain activities are also being performed under the other Separate Agreements.

3.2 Project Management. Lonza has appointed a project team responsible for overseeing the Project Plan, and a project manager as the principal point of contact with Customer pursuant to the 2K Development Agreement, and such project team and project manager shall continue to oversee the Services and other activities pursuant to this Agreement. The project team shall have regular teleconferences with Customer to discuss the progress of the Services, the expectation of the Parties being that these will usually take place on a weekly basis or as otherwise agreed by the Parties. Lonza may change its project team and project manager from time to time upon written notice to Customer. In the event that any dispute cannot be resolved by the project team, such dispute shall be escalated to the Joint Steering Committee. Lonza's project team shall coordinate closely with the project teams under the Separate Agreements.

3.3 Joint Steering Committee. The Parties have appointed a joint steering committee ("Joint Steering Committee") pursuant to the 2K Development Agreement. Such Joint Steering Committee shall continue to perform its applicable functions in relation to this Agreement. The Joint Steering Committee shall meet once per calendar quarter, or at such other frequency as may be necessary and is mutually agreed by the Parties. Decisions of the Joint Steering Committee shall be made by consensus, with each Party having one (1) vote. In the event that a Joint Steering Committee cannot reach consensus with respect to a particular matter within its authority, such dispute shall be escalated to a senior executive of each of Customer and Lonza who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the senior executives shall be reduced to writing and signed by the Parties and shall then be conclusive and binding on the Parties. The Joint Steering Committee shall coordinate closely with the joint steering committees under the Separate Agreements.

The function of the Joint Steering Committee is to ensure the ongoing communication between the Parties and discuss any issues arising under this Agreement. In addition to the function described above, the Joint Steering Committee shall also take on the following responsibilities:

3.3.1 discuss and seek resolution of issues around management of the Services;

3.3.2 monitor timelines and milestones for the Services;

3.3.3 discuss and recommend any changes to the Services (although such changes will not take effect until they have been approved in writing by the Parties in accordance with Clause 16.2); and

3.3.4 discuss and seek resolution for any dispute regarding the terms of this Agreement.

4 Quality

4.1 Quality Agreement. Responsibility for quality assurance and quality control of Product shall be allocated between Customer and Lonza as set forth in the Quality Agreement. If there is a conflict between the terms and conditions of this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall prevail. Performance by Lonza of all of its obligations under the Quality Agreement will be considered covered by the Batch Price and no additional consideration is payable by Customer unless otherwise agreed between the Parties. For clarity, the foregoing does not require Lonza to provide regulatory support other than as set forth in this Agreement and the Quality Agreement.

4.2 Inspections and Audits. Provisions regarding inspections by Governmental Authorities and audits are set out in the Quality Agreement, and include the following:

4.2.1 Customer and its designated representatives shall have the right to witness, inspect and audit the performance of Lonza's obligations, at the times, number of occasions and for durations set forth in the Quality Agreement and as otherwise agreed by the Parties;

4.2.2 Customer shall have reasonable access to the facilities, data and records of Lonza which are related to this Agreement for the purpose of conducting such inspections and audits, and Lonza shall use reasonable endeavours to ensure that all External Laboratories provide similar access to the External Laboratories' facilities, data and records which are related to this Agreement for such purposes;

4.2.3 Customer will have the sole right to correspond with and submit regulatory applications and other filings to any Governmental Authorities to obtain approvals to import, export, conduct clinical trials with, and/or sell the Product, alone and/or in combination with other products when and as Customer may deem useful and/or necessary. Accordingly, except as otherwise required by Applicable Laws and Governmental Authorities' requirements, Lonza will not correspond directly with any Governmental Authority with respect to the Product without, in each instance, first obtaining Customer's prior written consent (not to be unreasonably withheld);

4.2.4 Lonza will permit any Governmental Authorities to conduct inspections of Lonza's Facilities as the Governmental Authorities may request, and will cooperate with the Regulatory Authorities with respect to the inspections and any related matters, in each case related to the Product;

4.2.5 Lonza shall notify Customer promptly if any Governmental Authority schedules an inspection or, without scheduling, begins an inspection at a Facility, in each case, with respect to, and/or that would be reasonably likely to affect, the Product, and allow Customer to be on site during such inspection; and

4.2.6 Customer shall have the right to review the specifications, grades and vendors of all Raw Materials and components used under this Agreement to manufacture the Product at the Facility.

4.3 Regulatory Support and Cooperation. Lonza shall, at the Price as set forth in the 2K Development Agreement, provide Customer with regulatory support and cooperation related to the Product, the Process and seeking and maintaining Approvals as reasonably requested by Customer from time to time.

4.4 Recalls. If Customer recalls any Product (voluntarily and/or by order of a Regulatory Authority) and/or is required to respond to inquiries of Governmental Authorities relating to the Products, Lonza shall provide reasonable assistance to Customer in connection with the same. Customer shall pay Lonza for such assistance, unless such recall and/or inquiry is due to Lonza's fault and/or Lonza is otherwise required to indemnify Customer in relation to such recall and/or inquiry pursuant to Clause 11.1.

5 Insurance

Each Party shall, during the Term and for [Redacted] after delivery of the last Product manufactured and/or Services provided under this Agreement, obtain and maintain at its own cost and expense from a qualified insurance company, comprehensive general liability insurance including contractual liability coverage and product liability coverage in the amount of at [Redacted]. Each Party shall provide the respective other Party with a certificate of such insurance upon reasonable request.

6 Forecasting, Ordering and Cancellation

6.1 Forecasting. Beginning on the Effective Date, and thereafter [Redacted], Customer will provide Lonza a rolling [Redacted] forecast of the quantity of Batches it desires Lonza to supply (a "Forecast"), with the first [Redacted] of each such Forecast binding on each Party (such amounts forecasted in the first [Redacted] of the Forecast, the "Binding Portion" of a Forecast). Any Batches which are forecast in the Forecast which are in excess of the Binding Portion shall not be binding but shall be subject to Lonza's available capacity and only become binding once accepted by Lonza. [Redacted].

6.1.1 Following receipt of a Forecast, Lonza shall notify Customer whether it has capacity available at the Facility at the requested time for the Batches set out in the Forecast and the Parties shall promptly discuss any modifications to the Forecast that may be necessary to enable Lonza to accommodate Customer's request for such Forecasted Batches, provided however that:

(a) any Batches set forth in the Project Plan pursuant to the 2K Development Agreement or otherwise set forth in a Separate Agreement shall be manufactured in accordance with the schedule set forth in the applicable Separate Agreement; and

(b) If Lonza does not have sufficient capacity to supply quantities of Product to Customer's Forecasts Lonza will be obligated to provide notice thereof to Customer [Redacted] after receiving such Forecast.

6.1.2 Once the Parties have agreed on a Forecast, Lonza shall provide Customer with written confirmation of its acceptance of such agreed-upon Forecast. The Binding Portion of each Forecast shall become a binding commitment on both Parties upon acceptance of such Forecast, subject to Lonza's right to reschedule and Customer's right to delay or cancel such Batches described in Clauses 6.3 and 6.4.

6.1.3 Customer will order Batches pursuant to written purchase orders. Lonza must accept Customer's purchase orders for quantities of Batches that are consistent with the terms of this Agreement and that do not exceed the Binding Portion of agreed upon Forecasts and will use commercially reasonable efforts to accept orders exceeding such quantities.

6.1.4 [Redacted].

6.2 Additional Services. To the extent that Customer wishes during the Term of this Agreement to instruct Lonza to undertake development and/or other services in relation to the Process and/or the manufacture of Product other than as expressly set forth in this Agreement, any Binding Order and/or any Separate Agreement, the Parties shall, acting in good faith and with due expedition, enter into a written amendment or statement of work to this Agreement (each, a "SOW") on terms to be agreed between the Parties, documenting the additional services required, the price to be charged for such services and any consequential revisions to the timescales for delivery of such services. No such SOW will be binding unless and until it is executed by both Parties. Any changes and/or amendments to each SOW must also be executed by both Parties.

6.3 Rescheduling.

6.3.1 Lonza shall have the right to:

(a) reschedule the Commencement Date of any Batch or date of commencement for any Services upon [Redacted] prior written notice to Customer, provided that the rescheduled Commencement Date for such Batch or date of commencement for such Services is [Redacted] from the Commencement Date or the original estimated Commencement Date in accordance with the applicable Binding Order; and

(b) reschedule the Commencement Date of any Batch or date of commencement for any Services upon reasonable prior written notice to Customer, provided that the rescheduled Commencement Date or date of commencement is [Redacted] from the Commencement Date or date of commencement originally estimated in the Project Plan.

If Lonza so reschedules any Batch, Lonza's obligation to provide storage for such Batch without charge pursuant to Clause 7.3 shall extend to the later of: (i) [Redacted] after the actual Release of such Batch; or (ii) [Redacted] after the date such Batch would have been Released if the Commencement Date had not been so rescheduled.

6.3.2 If Customer requests to change the Commencement Date of any Batch, Lonza will make all reasonable attempts to accommodate the request; provided, however, in the event that this change would impact other projects scheduled for occupancy in the designated suite or suites and/or Lonza is not able to secure a project for the manufacturing space, and for the same dates and duration that would have been occupied by Customer, Lonza shall provide Customer notice thereof and the proposed revised schedule, and, to the extent Customer confirms in writing its request to make such change after receiving such notice, the manufacture of Customer's Batch and/or performance of such Services for Customer may be delayed as set forth in the revised schedule in Lonza's notice. Any such delay requested by Customer of more than [Redacted] shall be considered a cancellation pursuant to Clause 6.4.

6.4 Cancellation of a Binding Order. Customer may cancel all or any part of a Binding Order upon written notice to Lonza, subject to the payment of a cancellation fee as calculated below (the "Cancellation Fee"):

6.4.1 In the event that Customer provides written notice of cancellation to Lonza [Redacted] prior to the Commencement Date of one (1) or more Batch(es), then [Redacted] of the Batch Price of each such Batch cancelled is payable;

6.4.2 In the event that Customer provides written notice of cancellation to Lonza [Redacted] prior to the Commencement Date of one (1) or more Batch, then [Redacted] of the Batch Price of each such Batch cancelled is payable; and

6.4.3 In the event that Customer provides written notice of cancellation to Lonza [Redacted] prior to the Commencement Date of one (1) or more Batch, then [Redacted] of the Batch Price of each such Batch cancelled is payable.

For the avoidance of doubt: (a) any Batches scheduled to commence [Redacted], after the date of a notice of Cancellation shall not incur any Cancellation Fee; (b) no cancellation of a Batch pursuant to any amendments to the Project Plan which the Parties may agree in accordance with the 2K Development Agreement shall constitute a cancellation and no Cancellation Fee set out in this Clause 2.8 shall apply; (c) no cancellation of a Batch by Customer as a result of a [Redacted] shall incur any Cancellation Fee; provided that [Redacted].

6.5 Payment of a Cancellation Fee. The Cancellation Fee shall be payable [Redacted] of date of an invoice (to the extent not disputed pursuant to Clause 6.7) which shall be issued by Lonza following receipt by Lonza of Customer's written notice of cancellation associated with the cancelled Batch or Services but no earlier than when such amounts would have been invoiced for such Batch pursuant to Clause 8.3 absent such cancellation. The Cancellation Fee shall be reduced by any payments that Customer has already made for the cancelled Batches and/or Services. In addition to the Cancellation Fee, Customer shall pay for all pass-through costs associated with the cancelled Batch and/or Services, including the costs of Raw Materials that Lonza has irrevocably incurred in accordance with a Binding Order and the Raw Materials Fee for such Raw Materials, in each case, that Customer would have otherwise been responsible for paying and/or reimbursing pursuant to this Agreement if such Batch had been manufactured without cancellation.

6.6 Replacement Project. Notwithstanding the foregoing, Lonza will use commercially reasonable efforts to secure a new project (but excluding any project for which, at the time of cancellation, there is a binding obligation on Lonza to conduct or reserve capacity) for manufacturing space and for the same dates and duration that would have been occupied by Customer; and then in such case the Cancellation Fee for each Batch cancelled that is replaced by a batch of the new project shall be reduced by [Redacted] of the fees associated with such replacement batch. Lonza shall use commercially reasonable efforts to identify and secure a new project(s) (but excluding any project for which, at the time of cancellation or delay, there is a binding obligation on Lonza to conduct or reserve capacity) to utilize resources reserved for cancelled or delayed Services and to the extent such resources were utilized the Cancellation Fee, as applicable, for cancelled and/or delayed Services shall be reduced by an amount [Redacted] of the fees associated with such alternative utilization of resources.

6.7 Disputes. If Lonza invoices Customer for a Cancellation Fee in accordance with Clause 6.5 and Customer disputes such invoice, the matter shall be referred to the Joint Steering Committee for attempted resolution with each Party cooperating to resolve such dispute and if the Joint Steering Committee does not resolve such dispute, upon Customer's request, Lonza shall permit an independent Third Party reasonably agreed upon by the Parties to inspect the books and records of Lonza to verify whether such Cancellation Fee was due, and if so, the amount thereof.

7 Delivery and Acceptance

7.1 Delivery. All Product shall be delivered [Redacted] (as defined by Incoterms® 2010) the Facility (the "Release"). With respect to any Customer Materials, title and risk of loss shall remain with Customer and shall not transfer to Lonza. Customer shall bear the risk of loss of any Customer Materials provided to Lonza, except Lonza shall bear the risk of loss through the negligence, neglect and/or intentional misconduct of Lonza and/or its Affiliate and/or Subcontractor of any Customer Material. With respect to Product, title and risk of loss shall transfer to Customer upon Release in accordance with this provision.

7.2 Certificates of Analysis and Compliance. Lonza shall deliver to Customer the Certificate of Analysis, Certificate of Compliance and such other documentation as is reasonably required and/or requested by Customer to meet all applicable regulatory requirements of the Governmental Authorities not later than the date of Release of such cGMP Batches; provided that Lonza may, upon notice to Customer, supply certain trade secret information, such as Lonza's media and feed formulation, directly to the relevant Governmental Authority instead of supplying it to Customer.

7.3 Storage. Customer shall arrange for shipment and take delivery of Product from the Facility, at Customer's expense, within [Redacted] after Release or pay applicable storage costs. Lonza shall provide storage for Product at no charge for up to [Redacted]; provided that any additional storage beyond [Redacted] will be subject to storage being made available at Lonza's sole discretion and, if so available, will be charged to Customer at Lonza's then-standard rates and will be subject to a separate agreement. In addition to Clause 8.2, Customer shall be responsible for all value added tax (VAT) and any other applicable taxes, levies, import, duties and fees of whatever nature imposed as a result of any storage (other than taxes on Lonza's income, employees and/or property).

7.4 Acceptance/Rejection of Batches.

7.4.1 Promptly following Release of a Batch, Customer shall inspect such Batch and shall have the right to test such Batch to determine if it is a Failed Batch. Customer shall notify Lonza in writing of any rejection of a Batch based on any claim that it is a Failed Batch within [Redacted] after Release, after which time all unrejected Batch(es) shall be deemed accepted. Notwithstanding the foregoing, if Customer and/or its designee first discovers that any Batch is a Failed Batch and such failure would not have been readily discoverable from a reasonable testing or review of the Products (collectively, "Latent Defects"), Customer shall have the continuing right to reject the Batch, provided it notifies Lonza of the Latent Defect within [Redacted] after the discovery of the Latent Defect provided that such Latent Defect is discovered within the normal shelf-life of the Batch.

7.4.2 For any Batch rejected by Customer, Lonza shall promptly, but in any event within thirty (30) days after notice of rejection is received by Lonza, conduct and complete an initial root cause analysis to determine, or establish a plan for determining, the causes of the failure or non-conformity of the Batch. If, pursuant to such initial analysis, Lonza reasonably determines a longer period of time is needed to complete the full root cause analysis, Lonza shall complete such full analysis within a mutually agreed timeframe. Upon completion of such full analysis, Lonza shall provide Customer with a report detailing the root causes of such failure or non-conformity of such Batch and Lonza's action plan to remediate all issues identified in such report. Lonza shall give all members

of the Joint Steering Committee at least monthly reports on Lonza's execution of any such open action plan.

7.4.3 In the event that Lonza believes that a Batch has been incorrectly rejected for failure to conform with the Specifications, [Redacted]. Lonza may, at its expense, retain and test the samples of such Batch. In the event of a discrepancy between Customer's and Lonza's test results such that Lonza's test results show no failure or non-conformity to Specifications, or there exists a dispute between the Parties over the extent to which such failure and/or non-conformity to Specifications is attributable to a given Party, the Parties shall cause an independent laboratory promptly to review records, test data and perform comparative tests and analyses on samples of the Product that allegedly fails to conform to Specifications. Such independent laboratory shall be mutually agreed upon by the Parties. The independent laboratory's results shall be in writing and shall be final and binding save for manifest error. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules. The Party against whom the independent laboratory rules will be required to reimburse the other Party for shipping, storage and other similar out-of-pocket expenses incurred by the other Party in connection with such rejected Batch.

7.4.4 Lonza shall, at Customer's sole discretion, replace or provide a full refund for any Failed Batch, [Redacted] (collectively "Lonza Responsibility"). Replacement(s) for Failed Batches shall be made by Lonza as soon as reasonably possible (after confirmation of Lonza Responsibility if a determination of Lonza Responsibility is required). If Customer elects to have a Failed Batch replaced, Customer shall pay for such replacement Batch and the Raw Materials used therein (and any money Customer paid towards the Failed Batch (including for Raw Materials and any Raw Material Fees) shall be credited to the cost of the replacement Batch and related Raw Materials used in the replacement Batch). For clarity, no separate and/or additional Raw Material Fee shall be payable with respect to Raw Materials used to replace a Failed Batch that is a Lonza Responsibility and the Batch Price for a replacement of a Failed Batch shall be no greater than the Batch Price for the Failed Batch. If any replacement Batch provided as replacement for a Failed Batch also fails to conform with the Specifications and/or was not manufactured in accordance with cGMP, the Master Batch Record and the Quality Agreement, then, at Customer's sole discretion, Lonza shall either replace such Batch or shall refund the amounts paid by Customer for such Batch (including any amounts credited from the original Failed Batch).

7.4.5 Without limiting Clause 11.1, Customer acknowledges and agrees that its sole remedy with respect to a Failed Batch that is a Lonza Responsibility is as set forth in this Clause 7.4.5 and in furtherance thereof, Customer hereby waives all other remedies at law or in equity regarding the foregoing claims. Lonza shall not be responsible for the cost of Raw Materials or Customer Materials properly consumed in any Failed Batch except to the extent set forth in this Clause 7.4. Upon Customer's request, Lonza shall use commercially reasonable efforts to schedule for as soon as reasonably possible the manufacture and supply of a replacement Batch for any Failed Batch that is not a Lonza Responsibility provided that Customer shall pay for such replacement Batch and the Raw Materials used therein.

7.5 Order Fulfillment

7.5.1 If Lonza is unable to deliver to Customer any Batch ordered by Customer by its final agreed scheduled delivery date (i.e., the agreed delivery date set at the time Lonza freezes its production schedule in advance of the applicable month in which production will start), due to a Failed Batch or otherwise, Lonza shall replace such undelivered Batches as soon as reasonably possible.

7.5.2 If, in any calendar year during the Term, Lonza is unable to deliver to Customer [Redacted] in such calendar year by their final agreed scheduled delivery dates, this shall be considered a "Supply Failure," unless such failure to deliver is due to the fault of Customer. If Lonza is unable to replace any Batch within [Redacted] after the Supply Failure first occurred, Customer may, at its option, cancel such Batch and Customer shall not be subject to any Cancellation Fee in respect of such Batch. [Redacted].

8 Price and Payment

8.1 Services. Pricing for the Services provided by Lonza are set out in Appendix A.

8.2 Taxes. Unless otherwise indicated in writing by Lonza, all Prices and charges are exclusive of value added tax (VAT) and of any other applicable taxes, levies, import, duties and fees of whatever nature imposed by and/or under the authority of any government and/or public authority and all such charges applicable to the Services (other than taxes on Lonza's income, employees and/or property) shall be paid by Customer. When sending payment to Lonza, Customer shall quote the relevant invoice number in its remittance advice. If Lonza is required to charge and remit any such taxes, it shall itemize all such taxes on the applicable invoice sent to Customer.

8.3 Invoices and Payments. Lonza shall issue invoices to Customer for [Redacted] of the Price for the Batches or Services upon commencement thereof and [Redacted] upon Release of applicable Batches or completion of applicable Services, unless otherwise agreed in the applicable accepted purchase order. Charges for Raw Materials and the Raw Materials Fee for each Batch shall be invoiced upon the Release of each Batch. [Redacted] for Resins plus the Raw Materials Fee relating to such Resins shall be invoiced upon receipt of applicable Resins by Lonza. All invoices are strictly net and payment of undisputed amounts must be made within [Redacted] of date of invoice.

8.4 Repeated Late Payments. If Customer fails to pay an undisputed invoice within [Redacted] after the due date as set out in Clause 8.3 on [Redacted] occasions, then Lonza shall have the option to change the payment terms such that [Redacted] of the Price for any stage of work shall be payable on commencement and the price for Raw Materials and Resins and the Raw Materials Fee shall also be payable [Redacted].

8.5 Late Payments. If in default of payment of any undisputed invoice on the due date, interest shall accrue on any amount overdue at the lesser of: [Redacted] interest to accrue on a day to day basis until full payment; and, upon any material default of payment of undisputed invoices, Lonza shall, at its sole discretion, and without prejudice to any other of its accrued rights, be entitled upon providing [Redacted] notice to suspend the provision of the Services and/or delivery of Product until all overdue undisputed amounts have been paid in full including interest for late payments.

8.6 Price Adjustments.

8.6.1 Not more than once per calendar year and [Redacted] Lonza may adjust the Price as follows: [Redacted] year. Lonza must give notice of any such Price increase on or before [Redacted] and such Price increase will be effective as

to any Batches for which the Commencement Date is on or after January 1 of the immediately following calendar year.

8.6.2 In addition to the above, subject to Customer's written consent (such consent not to be unreasonably withheld), the Price may be changed by Lonza, upon reasonable prior written notice to Customer (providing reasonable detail in support thereof), to reflect: (i) an increase in variable costs (such as energy and/or Raw Materials, but specifically excluding labor and property costs) [Redacted] (based on the initial Price or any previously amended Price and (ii) any material change in [Redacted] that substantially impacts Lonza's cost and ability to perform the Services.

8.6.3 Notwithstanding Clauses 8.6.1 and 8.6.2 above, if any SOW or amendment is executed pursuant to this Agreement, then the Price for the Services set forth in such SOW or amendment shall not increase [Redacted] following the date of such SOW or amendment. For clarity, [Redacted] of such SOW or amendment, the Price may be revised in accordance with Clauses 8.6.1 and 8.6.2.

8.7 Books and Records. Lonza shall, during the Term and for [Redacted] thereafter, keep complete, true and accurate books and records necessary for the accurate and complete calculation of the amounts invoiced for Services hereunder that are determined on a time and materials basis and/or the pass-through of costs. Upon Customer's request, Lonza shall promptly provide Customer's designated, internationally recognized independent accounting firm, which accounting firm must be reasonably acceptable to Lonza, with copies of such records, in order that such accounting firm can verify the applicable amounts invoiced to Customer hereunder. The accounting firm shall only share with Customer a summary report on its findings, and such report must also be shared with Lonza. If the accounting firm identifies any discrepancy between such amounts charged to Customer by Lonza, and the amount that should have been charged, Lonza shall promptly pay the amount of any overpayment to Customer, [Redacted] until repaid to Customer in full.

8.8 Yield Price Adjustment. [Redacted].

9 Intellectual Property

9.1 Background Intellectual Property. Except as expressly otherwise provided herein, neither Party will, as a result of this Agreement, acquire any right, title, and/or interest in any Background Intellectual Property of the other Party.

9.2 New Customer Intellectual Property. Subject to Clause 9.3, Customer shall own all right, title, and interest in and to any and all Intellectual Property that Lonza and its Affiliates, the External Laboratories and/or other contractors and/or agents of Lonza develops, conceives, invents, first reduces to practice and/or makes, solely and/or jointly with Customer and/or others, in the performance of the Services to the extent such Intellectual Property is directed to an improvement to the Product, Customer Material, Cell Line, Customer Information and/or Customer Background Intellectual Property, including all Intellectual Property that is solely a direct derivative of and/or improvement to the Product, Customer Material, Cell Line, Customer Information and Customer Background Intellectual Property (collectively, the "**New Customer Intellectual Property**"). For the avoidance of doubt, "New Customer Intellectual Property" shall include any material, processes and/or other items that solely embody, and/or that solely are claimed and/or covered by, any of the foregoing Intellectual Property, but excluding any New General Application Intellectual Property.

9.3 New General Application Intellectual Property. Notwithstanding Clause 9.2 and subject to the license granted in Clause 9.5, Lonza shall own all right, title and interest in Intellectual Property that Lonza and its Affiliates, the External Laboratories and/or other contractors and/or agents of Lonza, solely and/or jointly with Customer, develops, conceives, invents, and/or first reduces to practice and/or makes in the course of performance of the Services to the extent such Intellectual Property: (i) is generally applicable to the development and/or manufacture of chemical and/or biological products and/or product components; and/or (ii) is an improvement of, and/or direct derivative of, any Lonza Background Intellectual Property, in each case which does not include (and the use of which would not disclose) the Product, Customer Materials, Customer Information and/or Customer Background Intellectual Property, but excluding all Intellectual Property that is solely a direct derivative of and/or solely an improvement to the Product, Customer Material, Cell Line, Customer Information and Customer Background Intellectual Property ("**New General Application Intellectual Property**"). For the avoidance of doubt, "New General Application Intellectual Property" shall include any material, processes and/or other items that solely embody, and/or that solely are claimed and/or covered by, any of the foregoing Intellectual Property.

9.4 Further Assurances. Lonza hereby assigns to Customer all of its right, title and interest in any New Customer Intellectual Property. Lonza shall execute, and shall require its personnel as well as its Affiliates, External Laboratories and/or other contractors and/or agents and their personnel involved in the performance of the Services to execute, any documents reasonably required to confirm Customer's ownership of the New Customer Intellectual Property, and any documents required and/or reasonably requested by Customer, but excluding any document that is Lonza Information, to apply for, maintain and enforce any patent and/or other right in the New Customer Intellectual Property.

9.5 License to New General Applicable Intellectual Property. Lonza hereby grants to Customer a non-exclusive, world-wide, fully paid-up, revocable (solely upon Lonza's termination of this Agreement for Customer's uncurable material breach of this Agreement, but if Customer contests the claim of such material breach, the license will not be revoked unless and until such uncurable material breach is determined to have occurred in accordance with Clause 16.6), perpetual, transferable license, including the right to grant sublicenses, under the New General Application Intellectual Property: (a) to research, develop, make, have made, use, sell and import the Product and reasonable modifications, extensions and expansions of the Product but no other product; and/or (b) solely as it relates to the Product and reasonable modifications, extensions and expansions of the Product but no other product, to the extent necessary to exercise, exploit and/or otherwise fully enjoy Customer's rights in and to the New Customer Intellectual Property.

9.6 License to Perform Services. Customer hereby grants Lonza a non-exclusive, revocable license to use the Customer Information, Customer Background Intellectual Property and New Customer Intellectual Property during the Term solely for the purpose of fulfilling its obligations under this Agreement. Except as express set forth in the prior sentence, Lonza receives no license, right, title or interest in or to the Product, Customer Information, Customer Background Intellectual Property and/or New Customer Intellectual Property and all such rights are reserved by Customer.

9.7 License to the Process and License Back to Improvements.

9.7.1 Lonza hereby grants Customer a non-exclusive, revocable (solely upon Lonza's termination of this Agreement for Customer's uncurable material

breach of this Agreement, but if Customer contests the claim of such material breach, the license will not be revoked unless and until such uncurable material breach is determined to have occurred in accordance with Clause 16.6), worldwide license, with the right to grant sublicenses to Alternate Manufacturers, under the Lonza Information, and Lonza Background Intellectual Property incorporated into the Process to make, have made, use, sell, offer for sale and import the Product and reasonable modifications, extensions and expansions of the Product, provided such Product and reasonable modifications, extensions and expansions of the Product, but no other product, may only be made within the Approved Territory.

9.7.2 Customer hereby grants to Lonza and its Affiliates a non-exclusive, worldwide, royalty free, revocable (solely upon Customer's termination of this Agreement for Lonza's uncurable material breach of this Agreement, but if Lonza contests the claim of such material breach, the license will not be revoked unless and until such uncurable material breach is determined to have occurred in accordance with Clause 16.6) license, with the right to grant and authorize sublicenses to Third Parties, under Improvements to make, have made, use sell, offer for sale and import products and provide services, whether for itself or any Third Party. For the purposes of the foregoing, "Improvements" means any material enhancement and/or improvement made by Customer to the Lonza Information and/or Lonza Background Intellectual Property in the conduct of the Process transferred to it under this Agreement in accordance with Clause 9.8 to the extent such enhancement and/or improvement is severable from and does not utilize, disclose and/or reveal any Customer Background Intellectual Property and/or Customer Information.

9.8 Technology Transfer to Customer or Alternative Manufacturers.

9.8.1 Upon the written request of Customer and subject to the terms and conditions of this Clause 9.8 and provided that Customer is not in material breach of this Agreement (which material breach is incurable or has not timely been cured by Customer, as the case may be), and provided further that Lonza has not terminated this Agreement pursuant to Clause 13.2.2, Customer shall be permitted to transfer the Process to itself and/or another Alternate Manufacturer for the manufacture of the Product and reasonable modifications, extensions and expansions of the Product but no other product only within the Approved Territory. Unless approved in advance by Lonza in writing, Customer will only undertake such technology transfer for manufacture of the Product and reasonable modifications, extensions and expansions of the Product, but no other product, in the Approved Territory and only by an Alternate Manufacturer.

9.8.2 Customer shall provide written notice to Lonza in advance that it wishes to exercise its rights under this Clause 9.8 (the "Technology Transfer Notice"); the Technology Transfer Notice must be provided [Redacted] other than in connection with termination and/or notice of termination of this Agreement pursuant to an incurable material breach by Lonza under Clause 13.2. The Technology Transfer Notice shall provide reasonable details to Lonza about whether the proposed transfer of the Process is to Customer, to an Alternative Manufacturer or to another Third Party. In the case of a proposed transfer of the Process to a Third -Party or an Alternative Manufacturer, Customer shall [Redacted], Lonza shall commence performing its obligations under this Clause 9.8.

9.8.3 For any transfer permitted under this Clause 9.8, Lonza shall provide reasonably necessary documents [Redacted] to complete such technology transfer. A document will be considered "reasonably necessary" [Redacted] such document for the manufacture and approval of the Product.

Under no condition shall Customer be permitted to use and/or disclose for any purpose [Redacted].

9.8.4 In the event that Customer requires and/or reasonably requests technical support in relation to the Process transfer, then Lonza shall make such reasonable technical support available to Customer, with the scheduling of such technical support to be mutually agreed upon by the Parties.

9.8.5 Customer shall reimburse Lonza for any costs and expenses incurred by Lonza in connection with producing the documents and providing the support set forth in Clauses 9.8.3 and 9.8.4, with costs for Lonza's internal resources charged on a man day rate based upon Lonza's then-prevailing standard charge for technical support; provided that Lonza agrees to provide [Redacted].

9.8.6 As part of the technology transfer, Lonza shall advise Customer of all license from and/or payment to any Third Party that Lonza has received or pays in connection with the manufacture of the Product, but excluding any license or payment applicable to the general operation and maintenance of the Facility and Lonza equipment that are not unique or specific to the Products.

9.8.7 Lonza shall allow Customer reasonable access to, and rights to [Redacted] to the extent necessary and/or used for the production of Product by Lonza using some or all of the Process solely for purposes of [Redacted] for the Product and reasonable modifications, expansions and extensions of the Product, but no other product.

9.8.8 For clarity, the technology transfer process described in this Clause 9.8 shall be instead of and not in addition to the technology transfer process described in the BLA Agreement or 2K Development Agreement for the transfer of the Process for the Product [Redacted]. The foregoing does not limit any amounts due from Customer to Lonza as set forth in Clauses 9.8.1 through 9.8.7.

10 Warranties

10.1 Lonza Warranties. Lonza warrants that:

10.1.1 the Services shall be performed in accordance with all Applicable Laws and this Agreement;

10.1.2 upon Release, the Product in cGMP Batches meets the Specifications and was manufactured in accordance with cGMP, the Master Batch Record and the Quality Agreement, and title to all Product provided to Customer will pass to Customer free and clear of any security interest, lien and/or other encumbrance;

10.1.3 it and/or its Affiliate holds all necessary permits, approvals, consents and licenses to enable it to perform the Services at the Facility and it has the necessary corporate authorizations to enter into and perform this Agreement;

10.1.4 to the best of Lonza's knowledge and belief, without having conducted a freedom-to-operate analysis on use of the Customer Information, Customer Background Intellectual Property or Customer Materials, the conduct and the provision of the Services shall not infringe, misappropriate and/or violate (as the case may be) any proprietary and/or Intellectual Property rights of any Third Party;

10.1.5 Lonza will notify Customer in writing immediately if it receives and/or is notified of a claim from a Third Party that the use by Lonza (and/or Customer or other entity to which the Process is transferred pursuant to Clause 9.8) of the Process and/or the Lonza Know-How and/or the Lonza Patent Rights for Services infringes, misappropriates and/or otherwise violates any Intellectual Property and/or industrial property rights vested in a Third Party;

10.1.6 Lonza has never been debarred under the Generic Drug Enforcement Act of 1992, 21 U.S.C. Sec. 335a(a) and/or (b), and/or sanctioned by a Federal Health Care Program (as defined in 42 U.S.C. § 1320 a-7b(f)), including the federal Medicare and/or a state Medicaid program, and/or debarred, suspended, excluded, and/or otherwise declared ineligible from any Federal agency and/or program. In the event that during the Term of this Agreement, Lonza becomes debarred, suspended, excluded, sanctioned, and/or otherwise declared ineligible; Lonza agrees to immediately notify Customer. Lonza also agrees that in the event that it becomes debarred, suspended, excluded, sanctioned, and/or otherwise declared ineligible, it shall immediately cease all activities relating to this Agreement;

10.1.7 title to all Product and all New Customer Intellectual Property provided to Customer under this Agreement shall pass free and clear of any security interest, lien and/or other encumbrance; and

10.1.8 it shall perform all Services hereunder in a professional and workmanlike manner, with due care and in accordance with all regulatory requirements and standards and best practices prevailing in the industry, and it shall perform and document each Service in accordance with the applicable Specifications, Master Batch Record or SOW;

10.2 Customer Warranties. Customer warrants that:

10.2.1 Customer has and shall at all times throughout the Term of this Agreement have the right to supply the Cell Line, the Customer Materials and the Customer Information to Lonza and the necessary rights to license and/or permit Lonza to use the same for the sole purposes of performing the Services;

10.2.2 to the best of Customer's knowledge and belief, the use of the Customer Information, Customer Background Intellectual Property or Customer Materials by Lonza in the course of performance of Services shall not infringe, misappropriate or violate (as the case may be) any Intellectual Property rights of any Third Party;

10.2.3 Customer will promptly notify Lonza in writing if it receives or is notified of a formal written claim from a Third Party that Customer Information, Customer Materials and Customer Intellectual Property or that the use by Lonza thereof for the provision of the Services infringes, misappropriate or otherwise violates any Intellectual Property or other rights of any Third Party; and

10.2.4 Customer has the necessary corporate authorizations to enter into this Agreement.

10.3 DISCLAIMER: THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, AND ALL OTHER WARRANTIES, BOTH EXPRESS AND IMPLIED, ARE EXPRESSLY DISCLAIMED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

10.4 Debarment.

10.4.1 In the event that Customer receives notice from Lonza and/or otherwise becomes aware that a debarment, suspension, exclusion, sanction, and/or declaration of ineligibility action has been brought against Lonza; then Customer shall have the right to terminate this Agreement immediately; provided that if such event shall occur, Customer shall not have such right of termination if Lonza is disputing and defending such action and Lonza is otherwise able to perform its services in the manner required under this Agreement.

10.4.2 Lonza hereby certifies that it will not knowingly use in any capacity the services of any individual, corporation, partnership and/or association which has been debarred under 21 U.S.C. Sec. 335a(a) or (b), and/or listed in the DHHS/OIG List of Excluded Individuals/Entities and/or the General Services Administration's Listing of Parties Excluded from Federal Procurement and Non-Procurement Programs.

11 Indemnification and Liability

11.1 Indemnification by Lonza. Subject to Clause 11.5, Lonza shall indemnify Customer, its Affiliates, and their respective officers, employees and agents ("Customer Indemnitees") from and against any loss, damage, costs and expenses (including reasonable attorney fees) that Customer Indemnitees may suffer as a result of any Third-Party claim arising directly out of:

11.1.1 any breach of this Agreement and/or the Quality Agreement by Lonza, including the warranties given by Lonza in Clause 10.1;

11.1.2 the nonconformity of the Product to the Specifications itself being occasioned solely by reason of a breach of this Agreement by Lonza and/or the gross negligence and/or intentionally wrongful acts and/or omissions of Lonza;

11.1.3 the gross negligence and/or intentionally wrongful acts and/or omissions of Lonza and/or any Lonza Indemnitee; and/or

11.1.4 any allegation that the Services (excluding solely as a result of use of Customer Information, Customer Background Intellectual Property and/or Customer Materials supplied by and/or on behalf of Customer) infringes, misappropriates and/or otherwise violates any Intellectual Property rights of a Third Party;

except in each case to the extent that such claims resulted from the negligence, intentional misconduct and/or breach of this Agreement and/or the Quality Agreement by any Customer Indemnitees.

Notwithstanding the foregoing, Lonza shall have no obligations under this Clause 11.1 for any liabilities, expenses, and/or costs to the extent arising out of and/or relating to claims covered under Clause 11.2.

11.2 Indemnification by Customer. Subject to Clause 11.5, Customer shall indemnify Lonza, its Affiliates, and their respective officers, employees and agents ("Lonza Indemnitees") from and against any loss, damage, costs and expenses (including reasonable attorney fees) that Lonza Indemnitees may suffer as a result of any Third-Party claim arising directly out of:

11.2.1 any breach of this Agreement and/or the Quality Agreement by Customer, including the warranties given by Customer in Clause 10.2 above;

11.2.2 any claims alleging that the use of the Customer Information, Customer Background Intellectual Property and/or Customer Materials in the course of performance of Services infringes any Intellectual Property rights of a Third Party;

11.2.3 the manufacture, use, sale, or distribution of the Product by or on behalf of Customer, including any claims of product liability;

11.2.4 the gross negligence and/or intentionally wrongful acts and/or omissions of Customer and/or any Customer Indemnitee; or

11.2.5 any allegation that the use by Lonza of any Customer Information, Customer Background Intellectual Property and/or Customer Materials supplied by and/or on behalf of Customer for the purpose of this Agreement (excluding solely as a result of use by and/or on behalf of Lonza of Lonza Background Intellectual Property, Lonza Information and/or other material and/or information supplied by Lonza) infringes, misappropriates and/or otherwise violates any Intellectual Property rights of a Third Party;

except, in each case, to the extent that such claims resulted from the negligence, intentional misconduct and/or breach of this Agreement and/or the Quality Agreement by any Lonza Indemnitees.

Notwithstanding the foregoing, Customer shall have no obligations under this Clause 11.2 for any liabilities, expenses, and/or costs to the extent arising out of and/or relating to claims covered under Clause 11.1.

11.3 Indemnification Procedure. If the Party to be indemnified intends to claim indemnification under this Clause 11, it shall promptly notify the indemnifying Party ("Indemnitor") in writing of such claim. The Indemnitor shall have the right to control the defense and settlement thereof; provided, however, that: (i) the Indemnitor must obtain the prior written consent of the indemnitee (not to be unreasonably withheld) before entering into any settlement of such Third-Party claim; (ii) any indemnitee shall have the right to retain its own counsel at its own expense; and (iii) if the amount sought in any Third-Party claim (alone or in aggregate with all other Third-Party claims) (collectively, "Covered Claims") exceeds the amounts remaining payable by the Indemnitor pursuant to Clause 11.5 or the indemnitee otherwise believes that the total amount payable pursuant to the Covered Claims may exceed the amounts remaining payable by the Indemnitor pursuant to Clause 11.5, then the Parties shall discuss and use reasonable endeavours to agree who has conduct and control of the Covered Claims provided that if the Parties are not able to agree within thirty (30) days after the indemnitee provides Indemnitor with notice of its desire to take over control of such

Covered Claims (or such shorter period as necessary to preserve all of the indemnitee's rights), indemnitee may, at its election, retain full control over the such Covered Claims unless the Indemnitor executes a separate agreement with the indemnitee agreeing that it shall pay all amounts payable in connection with such Covered Claims irrespective of the limitation of liability in Clause 11.5. The indemnitee, its employees and agents, shall reasonably cooperate, at the Indemnitor's expense, with the Indemnitor in the investigation of any liability covered by this Clause 11. If the indemnitee elects to control the defense of any Covered Claim as permitted herein, the Indemnitor, its employees and agents, shall reasonably cooperate, at the Indemnitor's expense, with the indemnitee in the investigation of any liability covered by this Clause 11 with respect to such Covered Claim(s). The failure to deliver prompt written notice to the Indemnitor of any claim, to the extent prejudicial to its ability to defend such claim, shall relieve the Indemnitor of its obligation to the indemnitee under this Clause 11 only to the extent of such prejudice.

11.4 DISCLAIMER OF CONSEQUENTIAL DAMAGES. EXCEPT FOR EITHER PARTY'S BREACH OF CLAUSE 12 HEREOF, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, LOST PROFITS OR LOST REVENUES ARISING FROM OR RELATED TO THIS AGREEMENT, EXCEPT TO THE EXTENT RESULTING FROM FRAUD, GROSS NEGLIGENCE, WILLFUL BREACH OR INTENTIONAL MISCONDUCT. THE PARTIES AGREE THAT ANY AMOUNT ORDERED TO BE PAID BY A COURT OF COMPETENT JURISDICTION OR AGREED TO BE PAID PURSUANT TO A SETTLEMENT TO ANY THIRD PARTY IN CONNECTION WITH ANY CLAIM INDEMNIFIED PURSUANT TO CLAUSE 11.1 AND/OR 11.2 WILL BE DEEMED A DIRECT DAMAGE NOT SUBJECT TO THE ABOVE DISCLAIMER, EVEN IF SUCH DAMAGE IS OTHERWISE CHARACTERIZED IN SUCH CLAIM.

11.5 LIMITATION OF LIABILITY. SUBJECT ALWAYS TO CLAUSE 11.4, EACH PARTY'S LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED, [REDACTED]; EXCEPT TO THE EXTENT RESULTING FROM: (i) SUCH PARTY'S GROSS NEGLIGENCE, WILLFUL BREACH AND/OR INTENTIONAL MISCONDUCT; (ii) SUCH PARTY'S BREACH OF CLAUSE 12 (CONFIDENTIALITY); (iii) MISUSE OF THE OTHER PARTY'S INTELLECTUAL PROPERTY; AND/OR (iv) CUSTOMER'S OBLIGATION TO PAY FOR SERVICES PURSUANT TO CLAUSE 8.

11.6 Additional Exceptions. Nothing in this Agreement shall exclude and/or limit the liability of either Party for fraud, breach its obligations in respect of Intellectual Property pursuant to Clause 9 and/or for death and/or personal injury caused by its negligence and/or for any other liability that may not be limited and/or excluded as a matter of law.

12 Confidentiality

12.1 Confidentiality Obligations. A Party receiving Confidential Information (the "Receiving Party") agrees to strictly keep secret any and all Confidential Information received during the Term from and/or on behalf of the other Party (the "Disclosing Party") using at least the same level of measures as it uses to protect its own Confidential Information, but in any case at least commercially reasonable and customary efforts. Confidential Information shall include information disclosed in any form including in writing, orally, graphically and/or in electronic and/or other form to the Receiving Party, observed by the Receiving Party and/or its employees, agents, consultants, and/or representatives, and/or otherwise learned by the Receiving Party under this Agreement, which the Receiving Party knows and/or reasonably should know is confidential and/or proprietary.

12.2 Required Disclosures. Notwithstanding the foregoing, Receiving Party may disclose to any courts and/or other authorities Confidential Information which is and/or will be required pursuant to applicable governmental and/or administrative and/or public law, rule, regulation and/or order. In such case the Party that received the Confidential Information will, to the extent legally permitted, inform the other Party promptly in writing and cooperate with the Disclosing Party in seeking to minimize the extent of Confidential Information which is required to be disclosed to the courts and/or authorities.

12.3 Exceptions. The obligation to maintain confidentiality under this Agreement does not apply to Confidential Information, which:

12.3.1 at the time of disclosure was publicly available;

12.3.2 is and/or becomes publicly available other than as a result of a breach of this Agreement by the Receiving Party;

12.3.3 as the Receiving Party can establish by competent proof, was rightfully in its possession at the time of disclosure by the Disclosing Party without obligation of confidentiality and had not been received from and/or on behalf of Disclosing Party;

12.3.4 is supplied to a Party without obligation of confidentiality by a Third Party which was not in breach of an obligation of confidentiality to Disclosing Party and/or any other Third Party; and/or

12.3.5 is developed by the Receiving Party independently from and without use of the Confidential Information, as evidenced by contemporaneous written records.

12.4 Use and Return of Confidential Information. The Receiving Party will use Confidential Information only for the purposes of this Agreement and/or as otherwise permitted by this Agreement and will not make any use of the Confidential Information for its own separate benefit and/or the benefit of any Third Party including with respect to research and/or product development and/or any reverse engineering and/or similar testing; provided that Customer may test any materials provided by Lonza including Product and Cell Lines as necessary for Customer's quality assurance, quality control or compliance with Applicable Laws. The Receiving Party agrees to return and/or destroy promptly (and certify such destruction) on Disclosing Party's request all written and/or tangible Confidential Information of the Disclosing Party, except that one copy of such Confidential Information may be kept by the Receiving Party in its confidential files for record keeping purposes only.

12.5 Disclosure to Representatives. Each Party will restrict the disclosure of Confidential Information to such officers, employees, professional advisers, finance-providers, consultants, and representatives of itself and its Affiliates (and/or in the case of Customer, any Third Party it transfers the Process to in accordance with this Agreement) who have been informed of the confidential nature of the Confidential Information and who have a need to know such Confidential Information for the purpose of this Agreement and/or an applicable financing and/or acquisition. Customer may disclose Confidential Information of Lonza and its Affiliates to potential and actual acquirers provided such disclosure is limited to the terms of this Agreement and/or work product provided to Customer by Lonza as a consequence of the provision of the Services. Prior to disclosure to such persons, the Receiving Party shall bind its and its Affiliates' officers, employees, consultants, potential and actual acquirers and representatives to confidentiality and non-use obligations no less stringent than those

set forth herein. The Receiving Party shall notify the Disclosing Party as promptly as practicable of any unauthorized use and/or disclosure of the Confidential Information.

12.6 Responsibility for Representatives. The Receiving Party shall at all times be fully liable for any and all breaches of the confidentiality obligations in this Clause 12.6 by any of its Affiliates and/or the employees, consultants and representatives of itself and/or its Affiliates.

12.7 Equitable Relief. Each Party hereto expressly agrees that any breach and/or threatened breach of the undertakings of confidentiality provided under this Clause 12 by a Party may cause irreparable harm to the other Party and that monetary damages may not provide a sufficient remedy to the non-breaching Party for any breach and/or threatened breach. In the event of any breach and/or threatened breach, then, in addition to all other remedies available at law and/or in equity, the non-breaching Party shall be entitled to seek injunctive relief and any other relief deemed appropriate by the non-breaching Party.

13 Term and Termination

13.1 Term. This Agreement shall commence on the Effective Date and, unless terminated earlier as provided herein, shall remain in full force until [Redacted] after the Effective Date (the "Term").

13.2 Termination. This Agreement may be terminated as follows:

13.2.1 by Customer for any reason or no reason, with an effective date of termination no earlier than [Redacted] after the Effective Date, by providing at least [Redacted] advance written notice to Lonza;

13.2.2 by either Party if the other Party breaches a material provision of this Agreement and/or the Quality Agreement and fails to cure such breach to the reasonable satisfaction of the non-breaching Party [Redacted] following written notification of such breach from the non-breaching Party to the breaching Party; provided, however, that such [Redacted] period shall be extended as agreed by the Parties if the identified breach is incapable of cure [Redacted] and if the breaching Party provides a plan and timeline to cure the breach, promptly commences efforts to cure the breach and diligently prosecutes such cure (it being understood that this extended period shall be unavailable for any breach regarding non-payment);

Without limiting the generality of Clause 13.2.2, Lonza shall be deemed to have breached a material provision of this Agreement if: [Redacted];

13.2.3 by either Party, immediately, if the other Party becomes adjudicated insolvent, is dissolved and/or liquidated, makes a general assignment for the benefit of its creditors, and/or files or has filed against it, a petition in bankruptcy or has a receiver appointed for a substantial part of its assets and such action is not reversed within ninety (90) days;

13.2.4 by Customer pursuant to Clause 7.5.2 (Uncured Supply Failure);

13.2.5 by Customer pursuant to Clause 10.4.1 (Debarment); or

13.2.6 by Customer pursuant to Clause 14.1 (Force Majeure).

13.3 Consequences of Termination. In the event of termination:

13.3.1 by Customer pursuant to Clause 13.2.2 (Material Breach), 13.2.3 (Insolvency),13.2.4 (Uncured Supply Failure), 13.2.5 (Debarment) or 13.2.6 (Force Majeure):

(a) Lonza shall be compensated for Services and Batches rendered up to the date of termination, including in respect of any Product in-process;

(b) Lonza shall be compensated for all pass-through costs incurred through to the date of termination, including Raw Materials costs and Raw Materials Fees for Raw Materials used and/or purchased for use in accordance with Binding Orders; and

(c) if requested by Customer, Lonza shall supply to Customer Batches in accordance with Binding Orders placed prior to the effective date of termination, with such supply, including the payment therefore, to be undertaken in accordance with the terms of this Agreement.

13.3.2 by Customer pursuant to Clause 13.2.1 (Termination for Convenience) or termination by Lonza pursuant to Clauses 13.2.2 (Material Breach) or 13.2.3 (Insolvency), to the extent that termination results in the cancellation of any Services and/or Batches, Customer shall pay to Lonza a Cancellation Fee as per the terms of Clause 6.4 [Redacted], the date of termination being taken as the date of notice of cancellation for the purposes of the application of such Clause. For clarity, no other termination of this Agreement shall result in Cancellation Fees being owed;

13.3.3 Customer shall promptly return to Lonza any Lonza Know-How it may have received from Lonza pursuant to this Agreement, except to the extent that Customer retains the right to use such Lonza Know-How, including pursuant to Clause 9 and/or the GS Licence, any Separate Agreement and/or any other agreement between or among the Parties or any of their Affiliates subject to the terms of such agreements;

13.3.4 and/or expiration hereunder, Lonza shall promptly return to Customer all Customer Information and shall dispose of and/or return to Customer (at Customer's option and expense) the Customer Materials (and where supplied by Customer the Cell Line) and any materials therefrom, as directed by Customer;

13.3.5 and/or expiration hereunder, Lonza shall promptly return to Customer all remaining Raw Materials that Customer has paid for; and

13.3.6 notwithstanding Clause 6.5, any amounts payable by Customer pursuant to Clauses 13.3.1 or 13.3.2 shall be due [Redacted] of Customer's receipt of an undisputed invoice therefor from Lonza.

13.4 Survival. Expiration or termination of this Agreement for whatever reason shall not affect the accrued rights of either Lonza and/or Customer arising under and/or out of this Agreement and all provisions which are expressed to survive the Agreement shall remain in full force and effect including for the avoidance of doubt but not by way of limitation Clauses 5 (Insurance), 6.6 (Replacement Project), 7 (Delivery and Acceptance), 8.7 (Books and Records), 9 (Intellectual Property), 10 (Warranties), 11

(Indemnification), 12 (Confidentiality), 13.3 (Consequences of Termination), 13.4 (Survival), 15 (Notice) and 16 (Miscellaneous) (to the extent relevant).

14 Force Majeure

14.1 Excused Performance. If Lonza is prevented and/or delayed in the performance of any of its obligations under the Agreement by Force Majeure and gives written notice thereof to Customer specifying the matters constituting Force Majeure together with such evidence as Lonza reasonably can give and specifying the period for which it is estimated that such prevention and/or delay will continue, Lonza shall be excused from the performance and/or the punctual performance of such obligations as the case may be from the date of such notice for so long as such cause of prevention and/or delay shall continue. Provided that, if such Force Majeure persists for a period of [Redacted], Customer may terminate this Agreement by delivering written notice to the other Party.

14.2 COVID-19. The Parties acknowledge that the COVID-19 virus is currently causing global disruption, and while Lonza is not aware of any event as at the Effective Date that would prevent or delay Lonza in the performance of the Services, the Parties acknowledge that there is a risk that a Force Majeure event could arise as a consequence of the COVID-19 virus.

14.3 Definition. "Force Majeure" shall mean any reason and/or cause beyond Lonza's reasonable control affecting the performance by Lonza of its obligations under the Agreement, including any cause arising from and/or attributable to acts of God, strike, labor troubles, restrictive governmental orders and/or decrees, riots, insurrection, war, terrorists acts, and/or the inability of Lonza to obtain any required raw material, energy source, equipment and/or transportation.

14.4 Lonza Affiliates and Suppliers. With regard to Lonza, any such event of Force Majeure affecting services and/or production at its Affiliates and/or suppliers shall be regarded as an event of Force Majeure.

15 Notices

15.1 Notice Addresses. Any notice or other communication to be given under this Agreement shall be delivered personally and/or sent by email, or if email is not available, by first class pre-paid post addressed as follows:

15.1.1 [Redacted]
15.1.2 [Redacted]

or to such other destination as either Party hereto may hereafter notify to the other in accordance with the provisions of this Clause 15.

15.2 Timing of Delivery. All such notices and/or other communications shall be deemed to have been served as follows:

15.2.1 if delivered personally, at the time of such delivery;

15.2.2 if sent by email, upon confirmation of receipt by the recipient; or

15.2.3 if sent by first class pre-paid post, four (4) business days (Saturdays, Sundays and bank and/or other public holidays excluded) after being placed in the post.

16 Miscellaneous

16.1 Severability. If any provision hereof is or becomes at any time illegal, invalid and/or unenforceable in any respect, neither the legality, validity nor enforceability of the remaining provisions hereof shall in any way be affected and/or impaired thereby. The Parties hereto undertake to substitute any illegal, invalid and/or unenforceable provision by a provision which is as far as possible commercially equivalent considering the legal interests and the purpose of the provision.

16.2 Amendments. Modifications and/or amendments of this Agreement must be in writing and signed by the Parties. Lonza shall be entitled to instruct one or more of its Affiliates to perform any of Lonza's obligations contained in this Agreement, but Lonza shall remain fully responsible in respect of those obligations.

16.3 Assignment. Neither Party shall be entitled to assign, transfer, charge and/or in any way make over the benefit and/or the burden of this Agreement without the prior written consent of the other which consent shall not be unreasonably withheld and/or delayed, save that either Party shall be entitled without the prior written consent of the other Party to assign or transfer, this Agreement: (i) to an Affiliate; (ii) to any joint venture company of which Lonza or Customer, as the case may be, is the beneficial owner of at least fifty percent (50%) of the issued share capital thereof; (iii) to any company with which that Party may merge or by which that Party is acquired; or (iv) to any company to which that Party may transfer all or substantially all of its assets and undertakings pertaining to this Agreement. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

16.4 Publicity. The text of any press release and/or other communication to be published by and/or in the media concerning the subject matter of this Agreement shall require the prior written approval of both Lonza and Customer**.**

16.5 Governing Law. This Agreement is governed in all respects by the laws of the State of New York without regard to its conflicts of laws principles.

16.6 Dispute Resolution. All dispute, controversy and/or claim arising out of and/or in connection with this Agreement (each, a "Dispute") shall be finally settled under the Rules of Arbitration (the "Rules") of the International Chamber of Commerce ("ICC") by three arbitrators appointed in accordance with the Rules, as modified hereby. Each Party shall appoint one arbitrator. The third arbitrator, who shall act as president of the arbitral tribunal, shall be jointly nominated by the other two arbitrators within 30 days of the confirmation of the second arbitrator. If the president of the arbitral tribunal is not nominated within this time period, such arbitrator shall be appointed in accordance with the Rules. The seat or place of arbitration shall be in the Borough of Manhattan, New York, New York, USA. The arbitration shall be conducted and the award shall be rendered in the English language. The arbitrators will have no authority to award any damages prohibited by this Agreement and/or any remedy that could not have been awarded by a state or federal court located in the in the Borough of Manhattan, New York, New York, USA. The arbitrators' decisions and awards shall be provided in writing and shall include the basis on which they are made. The award rendered by the arbitrators shall be final, non-appealable and binding on the Parties and may be entered and enforced in any court having jurisdiction over the Party against whom the award is being enforced and/or such Party's assets. During any Dispute, each Party agrees to continue to perform its obligations under this Agreement if and until such performance is excused pursuant to the resolution of such Dispute. In addition, each Party hereby submits to the non-exclusive jurisdiction of the state and

federal courts located in the Borough of Manhattan, New York, New York, USA for purposes of determining the arbitrability of any Dispute, causing such Party to appear for and participate in such arbitration and enforcing any award granted by the arbitrators, and each Party hereby submits to such jurisdiction. Notwithstanding the foregoing, if Lonza commits a Willful Breach, Customer may, at its election, bring and maintain any claim against Lonza for such Willful Breach against Lonza in any court of competent jurisdiction.

16.7 Entire Agreement. This Agreement contains the entire agreement between the Parties as to the subject matter hereof and supersedes all prior and contemporaneous agreements with respect to the subject matter hereof, excluding for clarity the Separate Agreements. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same document. Each Party acknowledges that an original signature and/or a copy thereof transmitted by email and/or by .pdf shall constitute an original signature for purposes of this Agreement.

16.8 Third Party Rights. The Parties to this Agreement do not intend that any term hereof should be enforceable by virtue of the Contracts (Rights of Third Parties) Act 1999 by any person who is not a party to this Agreement.

16.9 Non-Exclusive Nature of Remedies. Unless otherwise expressly set forth in this Agreement, no remedies set forth herein shall be considered an exclusive remedy. Pursuit or receipt of any remedies by a Party for breach of this Agreement by the other Party does not constitute an election of remedies by such Party to the exclusion of other remedies potentially available.

16.10 Successors. Subject to the restrictions on transfer contained in this Agreement, this Agreement will enure to the benefit of and be binding on the Parties and their respective successors and permitted assigns.

* * * * * * *

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be executed by its duly authorized representative effective as of the date written above.

LONZA AG

By: _____
Name
Title

By: _____
Name
Title

ALLAKOS, INC.

By: _____
Name:
Title:

APPENDIX A
[Redacted]

APPENDIX B
[Redacted]

APPENDIX C
[Redacted]

APPENDIX D
[Redacted]

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements:

(1) Registration Statement (Form S-3 No. 333-233018) of Allakos Inc.,
(2) Registration Statement (Form S-8 No. 333-226247) pertaining to the 2018 Equity Incentive Plan, the 2018 Employee Stock Purchase Plan and the amended 2012 Equity Incentive Plan of Allakos Inc.
(3) Registration Statement (Form S-8 No. 333-231276) pertaining to the 2018 Equity Incentive Plan, and the 2018 Employee Stock Purchase Plan
(4) Registration Statement (Form S-8 No. 333-236631) pertaining to the 2018 Equity Incentive Plan, and the 2018 Employee Stock Purchase Plan

of our reports dated March 1, 2021, with respect to the financial statements of Allakos Inc. and the effectiveness of internal control over financial reporting of Allakos Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Redwood City, California
March 1, 2021

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert Alexander, certify that:

1. I have reviewed this Annual Report on Form 10-K of Allakos Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2021

By: /s/ Robert Alexander

Robert Alexander
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Adam Tomasi, certify that:

1. I have reviewed this Annual Report on Form 10-K of Allakos Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2021

By: /s/ Adam Tomasi

Adam Tomasi, Ph.D.
President, Chief Operating Officer and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Allakos Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2021

By: /s/ Robert Alexander

Robert Alexander
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Allakos Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2021

By: /s/ Adam Tomasi

Adam Tomasi, Ph.D.
President, Chief Operating Officer and Chief Financial Officer
(Principal Financial and Accounting Officer)