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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

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.)**
825 Industrial Road, Suite 500 San Carlos, California	**94070**
(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. ☐

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

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

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

The aggregate market value of the 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, 2023 was $287.5 million.

The number of shares of Registrant's Common Stock outstanding as of February 29, 2024 was 87,873,995.

Portions of the Registrant's Definitive Proxy Statement relating to the registrant's 2024 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 2023 fiscal year ended December 31, 2023.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, development plans, ongoing and planned future preclinical studies and clinical trials, future results of ongoing and planned clinical trials, expected research and development costs, regulatory strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, investors can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- our plans to develop, manufacture and commercialize AK006 and our other product candidates, including our targeted clinical indications, intellectual property strategy, sales and marketing objectives and infrastructure capabilities;
- the timing, focus and clinical indications of our preclinical studies and clinical trials, and the reporting of data from those trials;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the expected patient enrollment in our clinical trials;
- the impact that the adoption of new accounting pronouncements will have on our financial statements;
- the beneficial characteristics, safety, efficacy and therapeutic effects of AK006 or our other product candidates;
- the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for AK006 or our other product candidates for various diseases;
- our ability to obtain and maintain regulatory approval of AK006 or our other product candidates;
- our continued reliance on third-parties to manufacture our product candidates and conduct additional clinical trials of AK006;
- our ability to obtain, maintain, or negotiate favorable terms of any collaboration, partnership, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize AK006 and our other product candidates;
- our intentions with respect to future sales and marketing plans;
- the total reduction in force related to our 2024 Reorganization Plan;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the need for additional financing, and our ability to obtain such financing on terms that are favorable to the Company and its stockholders;
- our expectations regarding financial performance, including revenues, expenses and net losses, and impacts from our reorganization plans and manufacturing development efforts of the foregoing;
- the sufficiency of our existing cash, cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements;
- the costs associated with being a public company; and
- our anticipated uses of our existing cash, cash equivalents and marketable securities.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" included in Part I, Item 1A and elsewhere in this Annual Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, investors should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

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

PART I

Item 1. Business.

Overview

We are a clinical stage biotechnology company developing therapeutics which target immunomodulatory receptors present on immune effector cells involved in allergic, inflammatory and proliferative diseases. Activating inhibitory receptors allows us to directly target cells involved in disease pathogenesis and, in the setting of allergy and inflammation, has the potential to result in broad inhibition of inflammatory cells. In the setting of proliferative diseases, blocking the inhibitory function of the receptors could restore the immune cells' ability to identify and kill proliferative cells. Our most advanced product candidate, AK006, is currently in a Phase 1 clinical trial.

AK006 targets Siglec-6, an inhibitory receptor expressed selectively on mast cells, a type of white blood cell that is widely distributed in the body and plays a central role in the inflammatory response. Binding of AK006 to Siglec-6 is designed to activate the native inhibitory function of the receptor which in turn reduces mast cell activation. In preclinical studies, AK006 inhibited multiple modes of mast cell activation, including immunoglobulin E ("IgE"), interleukin-33 ("IL-33"), tyrosine kinase receptor ("KIT"), complement component 5a ("C5a"), and mass-related G protein-coupled receptor-X2 ("MRGPR-X2"), resulting in the deep suppression of mast cell activation. In addition to mast cell inhibition, AK006 reduced human tissue mast cells via antibody-dependent cellular phagocytosis ("ADCP") in the presence of activated macrophages.

CSU is an inflammatory skin disease believed to be caused by the inappropriate activation of mast cells via IgE-dependent and IgE-independent pathways in the skin. Symptoms of CSU include frequent and unpredictable eruption of hives, severe itching and swelling. First-line treatment consists of H1 antihistamine medication; however, a significant number of patients do not receive adequate benefit from such medication even at up to four times the labeled dose. In the United States, it is estimated that there are approximately 800,000 adults with moderate-to-severe CSU whose disease is refractory to antihistamines. There is only one FDA approved therapy for patients who are refractory to antihistamines, omalizumab, which binds IgE. Because AK006 inhibits both IgE-dependent and IgE-independent modes of mast cell activation, it has the potential to treat a broad CSU population or show greater symptom improvement.

In the third quarter of 2023, we began dosing healthy volunteers in a randomized, double-blind, placebo-controlled Phase 1 study of AK006. The Phase 1 study of AK006 consists of single ascending dose ("SAD") and multiple ascending dose ("MAD") cohorts in healthy volunteers, as well as well as a cohort in patients with CSU who will be administered AK006 via intravenous infusion. AK006 has been well-tolerated to date and has completed the SAD portion of the study. We expect to report SAD and MAD safety, pharmacokinetics ("PK") and pharmacodynamic ("PD") results in the second quarter of 2024.

As part of the Phase 1 study, we plan to collect skin biopsies from healthy volunteers dosed with AK006 which will allow us to determine the amount of AK006 that is bound to the Siglec-6 receptor on skin mast cells (also known as the receptor occupancy). Given that CSU is believed to be caused by inappropriately activated skin mast cells, this information will allow us to assess AK006's ability to reach the pathogenic cell type in the target tissue and to determine whether AK006 is achieving receptor occupancy levels consistent with the levels required for inhibition in preclinical studies. Following the SAD and MAD portions of the Phase 1 AK006 study in healthy volunteers, we plan to initiate a randomized, double-blind, placebo-controlled cohort of patients with CSU. We expect data from the CSU cohort to be available at year end 2024.

We have also developed a formulation of AK006 for subcutaneous ("SC") administration. As part of the Phase 1 study, we are administering SC AK006 to a cohort of healthy volunteers. We expect to report SC AK006 safety, PK, and PD data, including bioavailability as well as Siglec-6 receptor occupancy in skin biopsy samples, during the third quarter of 2024. Pending positive data from the SC cohort, we plan to use the SC formulation in subsequent AK006 clinical trials.

We had also been developing lirentelimab (AK002) and, in conjunction with the Phase 2 lirentelimab results in atopic dermatitis and chronic spontaneous urticaria, we announced in January 2024 that we no longer plan to pursue further development of lirentelimab. Accordingly, we implemented a reorganization plan to reduce operating costs and better align our workforce with our current clinical development plans focusing on AK006 (the "2024

Reorganization Plan"). Lirentelimab had been administered in more than 1,000 patients, with approximately 500 patients exposed for six months or more. Lirentelimab had generally been well tolerated with no long-term safety findings to date.

Understanding the Foundation of Our Approach

Background on Mast Cells and Siglec-6

Mast cells are involved in many inflammatory conditions and therefore represent attractive drug targets. Mast cells 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 in the center of multiple aspects of the inflammatory response.

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 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.

Mast cells produce a broad range of inflammatory mediators including vasoactive amines, bioactive lipids, proteases, cytokines and chemokines and express many immunologically important cell surface receptors. As a result, mast cells are involved in both innate and adaptive immune responses and participate in both acute and chronic inflammation. Because of the inflammatory mediators they release and their ability to recruit and activate other immune cells through expression of chemokines and cytokines, mast cells are believed to drive symptoms in a number of diseases.

Agents targeting mast cell receptors or secretion products have shown utility in the treatment of a number of diseases including chronic urticaria, atopic dermatitis, severe asthma, chronic rhinosinusitis, eosinophilic gastrointestinal diseases, and indolent systemic mastocytosis, highlighting the pathogenic roles of mast cells.

Siglec-6 is an inhibitory receptor that our research shows is selectively expressed on mast cells. Because Siglec-6 is expressed in high abundance on mast cells, it presents a novel way to selectively target this important immune cell. As an inhibitory receptor, the natural function of Siglec-6 is to counteract activating signals within mast cells that lead to an inflammatory response. As a result, agonist antibodies that target Siglec-6, such as AK006, have the potential to inhibit multiple modes of mast cell activation and to reduce the secretion of the broad range of inflammatory mediators secreted by mast cells. By targeting Siglec-6, we are seeking to produce drugs with advantages over agents that target a single mast cell secretion product or activation pathway.

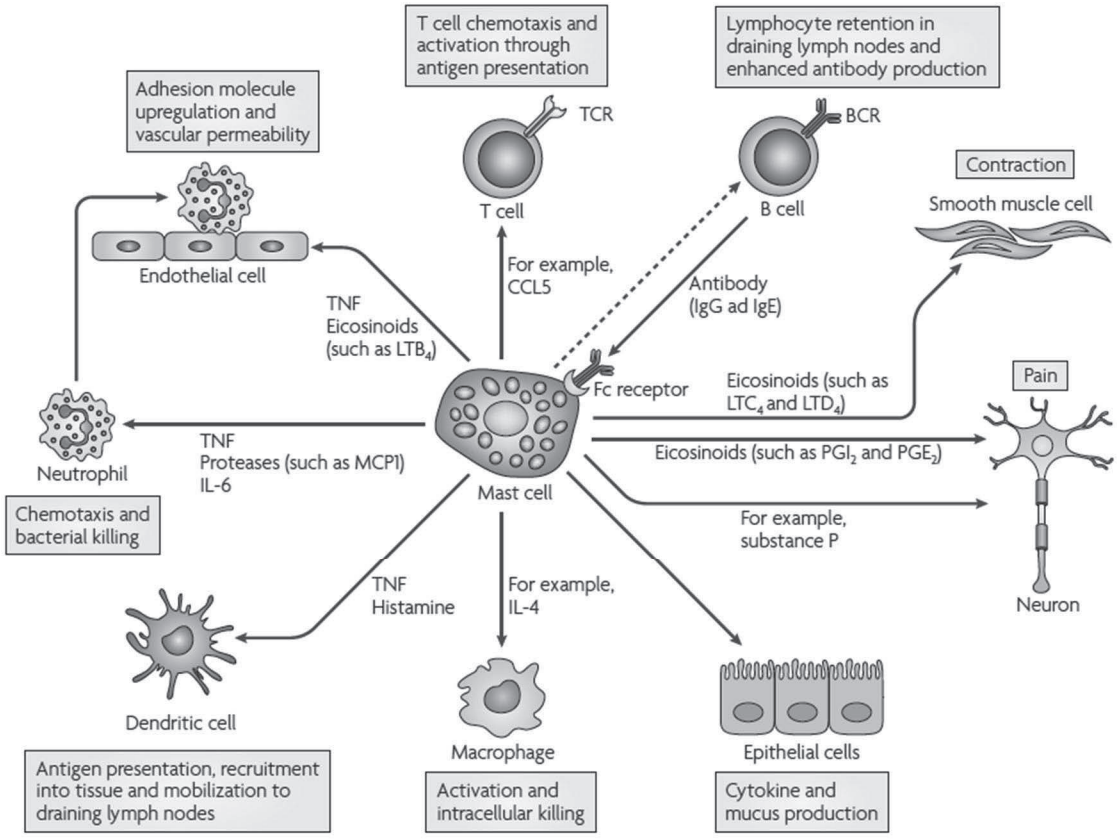
Mast cells are Effector Cells That are Central to Initiating and Maintaining Inflammatory Responses

Mast cells 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-4 and IL-13 and viruses through Toll-Like Receptors. In response to these and other activating signals, mast cells 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 are the key cause of tissue damage and contribute to tissue fibrosis.* Mast cell secretions are toxic to surrounding cells and break down tissues, resulting in fibrosis and tissue remodeling.
- *Mast cells drive inflammation by signaling to other cells of the immune system.* Mast cells 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 1. Mast Cell Functions



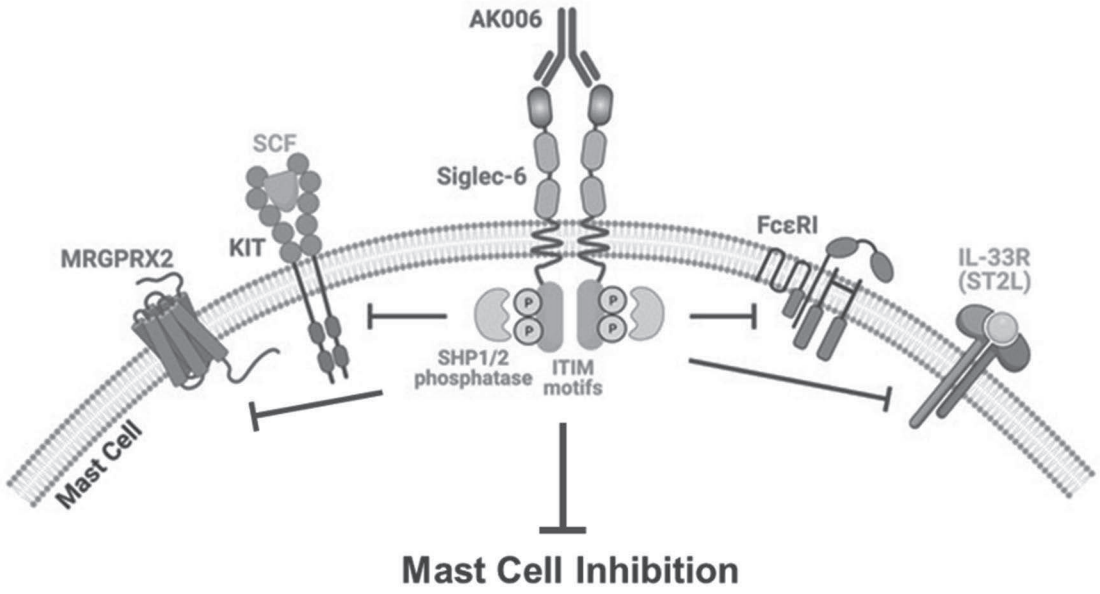
Due to their ability to respond to signals from multiple cell types and elicit responses from others, mast cells mediate the immediate hypersensitivity and late phase responses responsible for allergies and many innate and adaptive immune responses.

Siglec-6 is an Attractive Target for Mast Cell Driven Diseases

Siglec-6 (sialic acid immunoglobulin-like lectin 6) is a constitutively expressed inhibitory receptor that is found on the surface of mature mast cells. The physiological function of Siglec-6 is to provide an inhibitory signal to mast cells thereby reducing or preventing mast cell activation. Siglec-6 exerts these effects through an intracellular immunoreceptor tyrosine-based inhibitory motif ("ITIM").

ITIM bearing receptors antagonize activating receptors and consequently have important roles in regulating the immune system. The inhibitory function is derived from the ability of the ITIMs to recruit SH2 domain-containing phosphatases which work to oppose activating signals driven by kinase signaling cascades. Disrupting kinase signaling cascades has been a successful strategy for treating inflammatory diseases as evidenced by approved drugs which target JAK, KIT, BTK, SYK, and others. However, often these kinase signaling pathways are active in multiple cell types, which can result in unintended side effects when disrupted. In contrast, targeting the ITIM signaling cascade (via Siglec-6) has the potential to counteract a broad array of activating signals, including IgE, IL-33, MRGPR-X2, and KIT, which could allow for the treatment of multiple mast cell-driven diseases.

Figure 2. AK006 Triggers Potent Inhibition of Mast Cells



AK006 Binds to Siglec-6

AK006 was designed to take advantage of the selective expression pattern and inhibitory function of Siglec-6, an inhibitory receptor found on mast cells. AK006 is a humanized IgG1 monoclonal antibody which activates the inhibitory receptor Siglec-6. AK006 is directed to an extracellular epitope of the Siglec-6 receptor that was identified for its ability to generate strong inhibitory signals to mast cells. Furthermore, AK006 was engineered to have higher cell surface residence time which may increase mast cell inhibition. In preclinical studies, AK006 inhibited multiple modes of mast cell activation, including IgE, IL-33, KIT, C5a, and MRGPR-X2, resulting in the broad suppression of inflammation. In addition to mast cell inhibition, AK006 reduced human tissue mast cells via ADCP phagocytosis in the presence of activated macrophages.

Our Strategy

AK006 has shown activity in preclinical studies including a broad array of animal disease models of mast cell diseases. We have prioritized our AK006 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, operations and finance.

The key elements of our strategy are to:

- ***Evaluate AK006 in healthy volunteers.*** AK006 is currently being evaluated in a Phase 1 SAD and MAD study in healthy volunteers. The study is designed to assess safety, PK and PD of AK006. As part of the phase 1 study, we plan to collect skin biopsies from healthy volunteers dosed with AK006 which will allow us to look at the amount of AK006 that is bound to the Siglec-6 receptor on skin mast cells (also known as the receptor occupancy). Given that CSU is believed to be caused by inappropriately activated skin mast cells, this information will allow us to assess AK006's ability to reach the pathogenic cell type in the target tissue and to determine whether AK006 is achieving receptor occupancy levels consistent with the levels required for inhibition in preclinical studies. We expect to report data from the Phase 1 SAD and MAD portions of the study in the second quarter of 2024.
- ***Obtain Proof of Concept ("POC") with AK006 in CSU and other mast cell driven conditions.*** Allakos plans to test AK006 in a randomized, double-blind, placebo-controlled cohort of patients with chronic spontaneous urticaria ("CSU"). We expect data from the CSU cohort to be available at year end 2024. Chronic spontaneous urticaria is an inflammatory skin disease believed to be caused by the inappropriate

activation of mast cells in the skin. We believe there is a need for additional treatments for patients with CSU that are refractory to antihistamines. In addition, in 2024 we plan to initiate a clinical study with AK006 in an additional mast cell driven condition.

- ***Develop Subcutaneous formulation of AK006.*** We have also developed a formulation of AK006 for SC administration. As part of the Phase 1 study, we are administering SC AK006 to a cohort of healthy volunteers. We expect to report SC AK006 safety, PK, and PD data, including bioavailability as well as Siglec-6 receptor occupancy in skin biopsy samples, during the third quarter of 2024. Pending positive data from the SC cohort, Allakos plans to use the SC formulation in subsequent AK006 clinical development.
- ***Build therapeutic pipeline.*** Our research is focused on immunomodulatory receptors present on immune effector cells involved in allergic, inflammatory and proliferative diseases. Activating these immunomodulatory receptors allows us to directly target cells involved in disease pathogenesis and, in the setting of allergy and inflammation, has the potential to result in broad inhibition of inflammatory cells. In the setting of proliferative diseases, blocking the inhibitory the function of the receptors could restore the immune cells' ability to identify and kill proliferative cells. Following this approach, we have developed AK006 and have research programs directed at other immunomodulatory targets.

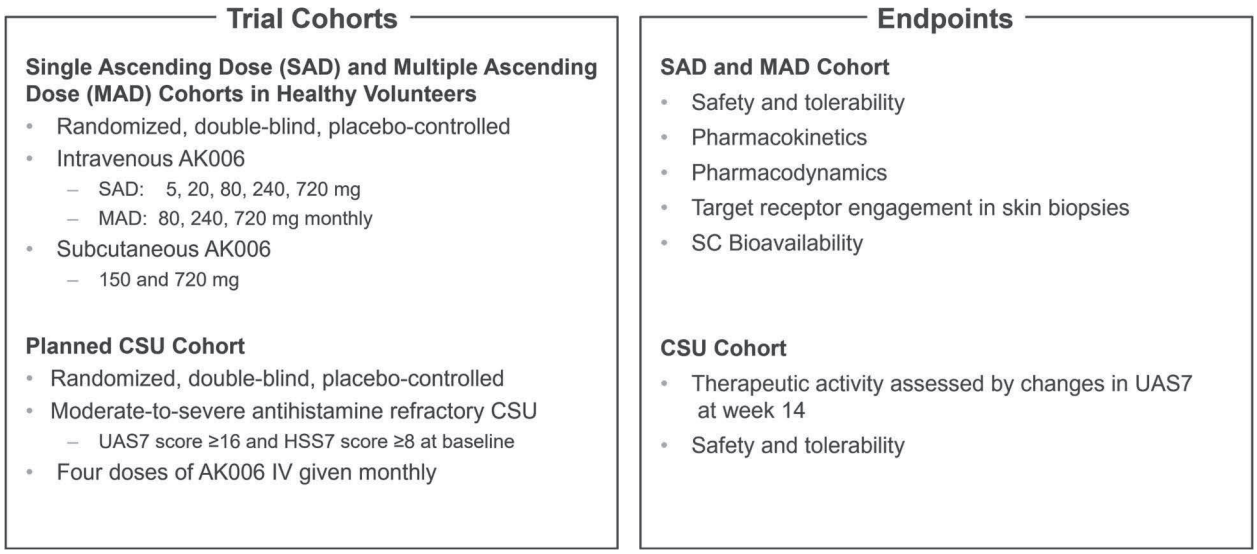
AK006 Clinical Development

We are developing AK006 for the treatment of CSU and potentially other indications. AK006 has completed extensive preclinical testing and, in these studies, we have demonstrated that binding of AK006 to Siglec-6 inhibits multiple modes of mast cell activation, including IgE, IL-33, KIT, C5a, and MRGPR-X2, resulting in the deep suppression of mast cell activation. In addition to mast cell inhibition, AK006 reduced human tissue mast cells via ADCP in the presence of activated macrophages. AK006 is currently being evaluated in a Phase 1 study in healthy volunteers and we plan to initiate a Phase 1 cohort in patients with CSU.

In the third quarter of 2023, we began dosing healthy volunteers in a randomized, double-blind, placebo-controlled Phase 1 study of AK006. The Phase 1 study of AK006 consists of SAD and MAD cohorts in healthy volunteers as well as a cohort in patients with CSU who will be administered AK006 via intravenous infusion. We expect to report SAD and MAD safety, PK and PD results in the second quarter of 2024. Additional key measurements include Siglec-6 receptor occupancy data in skin biopsies. Following the SAD and MAD portions of the Phase 1 AK006 study in healthy volunteers, we plan to initiate a randomized, double-blind, placebo-controlled cohort of patients with CSU. We expect data from the CSU cohort to be available at year end 2024.

Allakos has also developed a formulation of AK006 for SC administration. As part of the randomized, double-blind, placebo-controlled Phase 1 study, we initiated a cohort in healthy volunteers who will be administered AK006 via SC formulation. We expect to report SC AK006 safety, PK, and PD results, including bioavailability as well as Siglec-6 receptor occupancy in skin biopsy samples, during the third quarter of 2024. Pending success in the SC cohort, we plan to use the SC formulation in all subsequent AK006 clinical development.

Figure 3. AK006 Phase 1 Study Design



Chronic Urticaria

Disease Overview

Chronic urticaria ("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. The most common forms of CU are chronic spontaneous urticaria ("CSU"), cholinergic urticaria and symptomatic dermatographism.

Urticaria symptoms are caused by the inappropriate activation of mast cells via IgE-dependent and IgE-independent pathways in the skin. IgE-dependent mast cell activation has been identified as a pathogenic driver of urticaria and agents which target this pathway have demonstrated therapeutic activity. More recently, mast cell activation through MRGPR-X2, an IgE independent mast cell activation pathway, has been implicated in urticaria disease pathogenesis. In urticaria, agents that target both IgE-dependent and IgE-independent modes of mast cell activation have the potential to work in a broader patient population or show greater symptom improvement.

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.

In the United States, it is estimated that there are approximately 800,000 adults with moderate-to-severe CSU whose disease is refractory to antihistamines. There is only one FDA approved therapy, omalizumab, with low (<10%) usage for these patients.

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 CSU patients who remain symptomatic despite antihistamine treatment, the only currently approved treatment is Xolair (omalizumab), a monoclonal anti-IgE antibody. Unfortunately, approximately 60% of CSU patients continue to have symptoms despite treatment with Xolair.

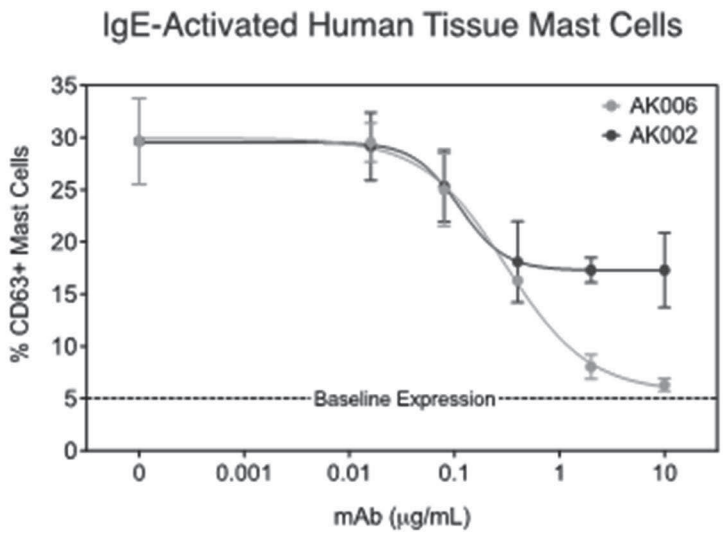
AK006 Preclinical Data

AK006 targets Siglec-6, an inhibitory receptor expressed selectively on mast cells. Binding of AK006 to Siglec-6 activates the native inhibitory function of the receptor which in turn reduces mast cell activation. In preclinical studies, AK006 inhibited multiple modes of mast cell activation, including IgE, IL-33, KIT, C5a, and MRGPR-X2, resulting in the broad suppression of inflammation. In addition to mast cell inhibition, AK006 reduced human tissue mast cells via ADCP. AK006 appears to have the potential to provide deeper mast cell inhibition than lirentelimab and, in addition to its inhibitory activity, to reduce mast cell numbers.

AK006 induces potent IgE mast cell inhibition in ex vivo human tissue

Activation of skin mast cells through the IgE receptor has been identified as contributing to the pathogenesis of CSU and other mast cell driven conditions. To evaluate AK006's ability to inhibit IgE activation of mast cells, we developed an IgE-mediated mast cell activation assay in human tissue. In this assay, mast cells are activated via high affinity IgE receptor, FcεRI, using an agonistic anti-FcεRI antibody and mast cell activation is evaluated by examining CD63 expression using flow cytometry. CD63 is an activation marker found on mast cell granules, high levels indicate that mast cells are actively degranulating. AK006 was able to provide near complete levels of inhibition in this preclinical experiment.

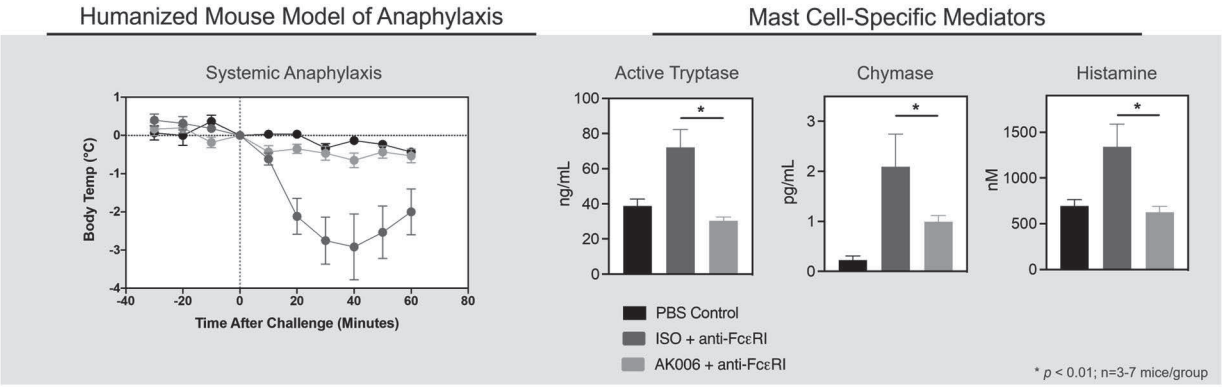
Figure 4. IgE-Mediated Mast Cell Activation in Human Tissue



AK006 inhibits systemic anaphylaxis in vivo

AK006 has been shown to inhibit mast cell activation in vivo using a systemic anaphylaxis mouse model. Administration of an anti-FcεRI antibody, to activate mast cells, induces systemic anaphylaxis in humanized mice. AK006 + anti-FcεRI treated mice demonstrated inhibition of an anaphylactic response compared to isotype control + anti-FcεRI treated mice that experienced an anaphylactic response. Moreover, AK006 treated mice displayed reduced levels of mast cell-derived mediators, including active tryptase, chymase and histamine. The data suggest that AK006 can inhibit IgE activation of mast cells in vivo as well as in vitro.

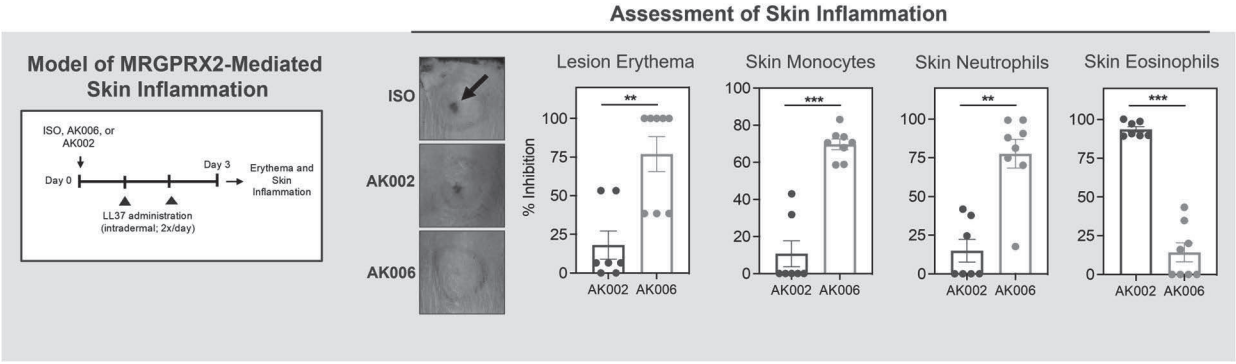
Figure 5. AK006 Protects Against Systemic Anaphylaxis in Humanized Mice



AK006 reduces MRGPR-X2 activation in skin inflammation model

AK006 has also been shown to inhibit MRGPR-X2 activation of mast cells in vivo. In a MRGPR-X2-mediated skin inflammation model, Siglec-6 transgenic mice or Siglec-8 transgenic mice were dosed with AK006, lirentelimab or an isotype. Mice were then injected intradermally with a substance (LL37) that activates MRGPR-X2, twice a day, for two days. This MRGPR-X2-mediated mast cell activation in mice induced erythema, as well as monocyte, and eosinophil infiltration. This data further demonstrates that treatment with AK006, but not lirentelimab, significantly reduces MRGPR-X2-mediated skin inflammation.

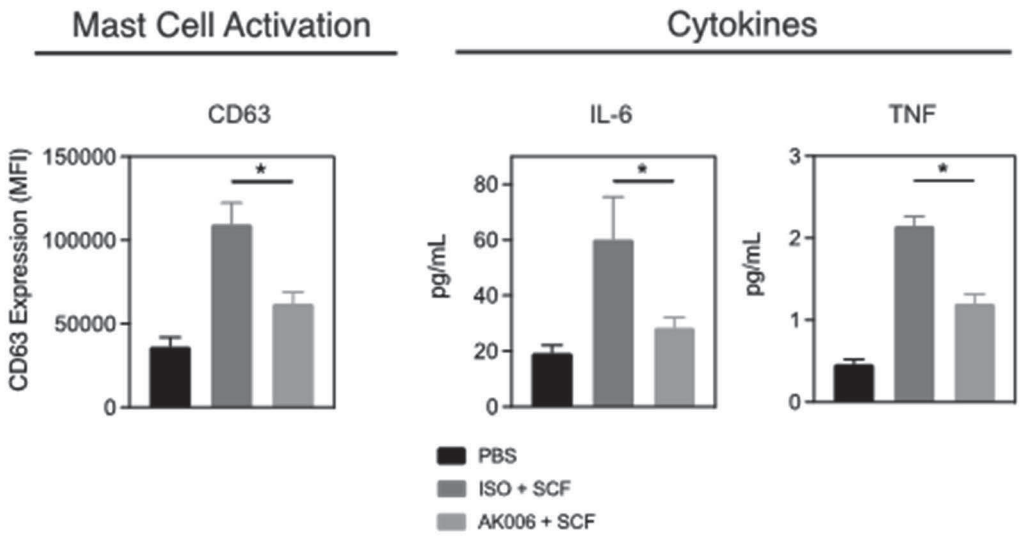
Figure 6. AK006 Reduces MRGPR-X2-Induced Skin Inflammation



AK006 inhibits KIT-mediated mast cell activation in vivo

AK006 also has been shown to inhibit KIT activation of mast cells in vivo. Administration of stem cell factor ("SCF"), a potent KIT activator, to Siglec-6 transgenic mice induces mast cell activation and inflammation. AK006 reduced KIT-mediated mast cell activation as assessed by CD63 expression compared to sham treated mice (mice that did not receive SCF). In addition, AK006 treated mice displayed reduced levels of inflammatory mediators (TNF and IL-6) compared to isotype control mice.

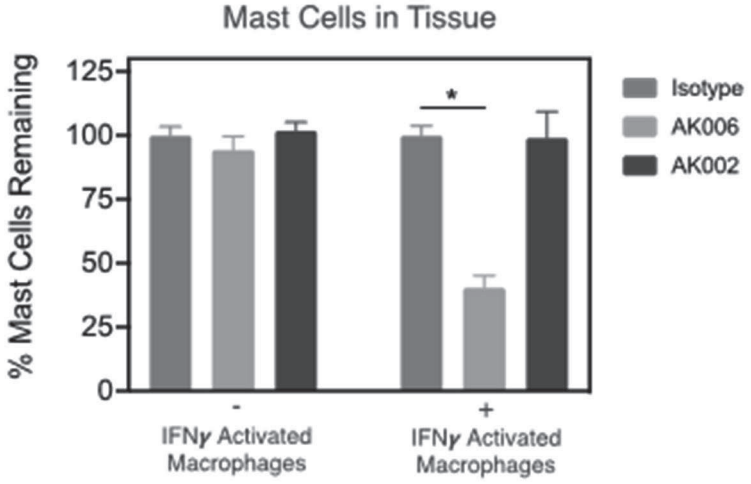
Figure 7. KIT-Mediated Mast Cell Activation and Inflammation in Siglec-6 Transgenic Mice



AK006 reduces mast cells in ex vivo human tissue

In human tissue processed into single cell suspensions and cultured overnight with or without human macrophages activated with IFNγ, AK006 significantly reduced the number of human tissue mast cells in the presence of activated macrophages relative to an isotype control mAb ("ISO"). This data suggests AK006 has unique activity that reduces mast cells via ADCP in the presence of activated effector cells, such as macrophages.

Figure 8. Mast Cell Numbers in *Ex Vivo* Cultured Human Tissue



The above data suggests that AK006 selectively targets mast cells and has the potential to induce broad inhibition of mast cell activation and reduce mast cell numbers. This profile could give AK006 increased therapeutic activity while potentially avoiding toxicities associated with less selective mast cell targeting drugs.

AK006 is currently being evaluated in a Phase 1 study in healthy volunteers and we plan to initiate a Phase 1 cohort in patients with CSU. We expect data from the CSU cohort to be available at year end 2024.

Pipeline Programs

We are developing additional antibodies targeting novel inhibitory receptors expressed on key disease-driving immune cells. These antibodies have demonstrated in vitro and in vivo activity in murine models and are being evaluated for further development.

Prior Clinical Programs with Lirentelimab

Lirentelimab has been administered to more than 1,000 patients, and approximately 500 patients have been exposed for six months or more. Lirentelimab has generally been well-tolerated in each of our clinical trials and has consistently demonstrated high levels of eosinophil depletion in blood and tissue. Lirentelimab showed activity in open label clinical studies in chronic urticaria, severe allergic conjunctivitis and indolent systemic mastocytosis. Moreover, the Phase 2 EG and/or EoD study with lirentelimab (ENIGMA 1) met all prespecified primary and secondary endpoints when compared to placebo and results were published in The New England Journal of Medicine. The ENIGMA 2, KRYPTOS and EoDyssey studies each met the histologic co-primary endpoint of those studies but did not meet the symptomatic co-primary endpoint when compared to placebo. More recently, the ATLAS and MAVERICK studies did not meet their primary endpoints. Due to the negative results in the recent clinical studies, we have halted lirentelimab development efforts.

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, and governmental agencies, as well as 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 specifically targets Siglec-6. The competition we may face with respect to each of the indications we are targeting with AK006 includes:

- ***Chronic Spontaneous Urticaria -*** Xolair (Roche and Novartis) is the only drug currently approved by the FDA for the treatment of CSU. Companies conducting studies in chronic spontaneous urticaria include: Novartis (remibrutinib), Sanofi (rilzabrutinib), Regeneron (dupilumab), and Celldex (barzolvolimab).

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.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe adverse events, and are more convenient or less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we can, which could result in our competitors establishing a strong market position before we are able to enter the market or could otherwise make our development more complicated.

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 geographic markets for the time being, and plan to build our own focused, specialty sales force to commercialize approved products in the United States. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of our product candidates. Clinical

data, the size of the addressable patient population, and the size of the commercial infrastructure and manufacturing needs may all influence or alter our commercialization plans. The responsibilities of the marketing and sales organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

Manufacturing

We 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, and we currently have no plans to establish any manufacturing facilities. We rely, and expect to continue to rely, on third-party manufacturers for the production, packaging, labeling, storage, and distribution of our product candidates for preclinical testing and in compliance with cGMP requirements for clinical trials under our guidance. In the case of AK006, to date we have relied on a single third-party manufacturer and we are currently in the process of developing alternative manufacturing capabilities. We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates if any of our product candidates 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.

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 after approval 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 nonclinical laboratory and animal tests that must be conducted in accordance with good laboratory practice ("GLP"), requirements;
- submission to the FDA of an 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 multiple 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 and payment of user fees, if applicable;
- 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;
- satisfactory completion of FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA or BLA to assure compliance with GCPs and the integrity of the clinical data;
- 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 development stage generally involves laboratory evaluation of drug chemistry, formulation and stability, as well as in vitro and animal studies to evaluate toxicity, assess potential safety and efficacy, assess the potential for adverse events, support subsequent clinical testing, 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. 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. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. 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. 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 human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Investigators must also provide information to the clinical trial sponsors to allow the sponsors to disclose any financial interests and arrangements to the FDA that could affect the reliability or integrity of data submitted. 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. The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements.

Prior to beginning the first clinical trial with a product candidate in the United States, the sponsor must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND submission is complete. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

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 be combined or overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected subjects 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 subjects 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 subjects 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 labeling and 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. The results of Phase 4 trials may confirm the effectiveness of a product candidate and may provide important safety information.

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. Since the start of the COVID-19 pandemic, the FDA has issued various COVID-19-related guidance documents for sponsors and manufacturers. President Biden ended the COVID-19 national and public health emergencies on May 11, 2023. The full impact of the termination of the public health emergencies on FDA and other regulatory policies and operations are unclear.

NDA/BLA Review Process

Following completion of the preclinical testing and 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.

The submission of an NDA or BLA requires payment of a substantial user fee to the FDA, unless otherwise exempted, such as in the case of an NDA for a drug with orphan drug designation. 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, for the FDA's fiscal year 2024, the user fee for an application requiring clinical data, such as an NDA or BLA, is approximately $4 million. PDUFA also imposes an annual program fee for human drugs and biologics of about $0.42 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.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use. It could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may offer conditional approval subject to, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

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 or for a select indication or use within the rare disease or condition for which it was designated, the product generally will be receiving 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.

In response to the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), in January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

Expedited Development and Review Programs

The FDA has various programs, including Fast Track designation, Breakthrough Therapy designation, accelerated approval and Priority Review designation, which are intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria.

The purpose of these programs is to ensure that therapies for serious conditions are approved and available to patients as soon as it can be concluded that the therapies' benefits justify their risks. Under the Fast Track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the IND submission for the drug candidate, but ideally no later than the pre-NDA meeting because many of the features of Fast Track designation will not apply after that time. To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need. The FDA will determine that a product has the potential to fill a medical need if it will provide a therapy where none exists or the condition is not adequately addressed by current available therapy. Fast Track designation provides additional opportunities for interaction with the FDA's review team and rolling review of NDA components before the completed application is submitted. For rolling submission, the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. The FDA may decide to rescind the Fast Track designation if it determines that the qualifying criteria no longer apply, and a sponsor may also withdraw Fast Track designation if the designation is no longer supported by emerging data or the drug development program is no longer being pursued.

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 sponsor may request Priority Review designation of an NDA for a drug that is intended to treat a serious condition at the time of

the original NDA (or efficacy supplement) submission. FDA may assign a Priority Review designation if FDA determines that the product, if approved, would provide a significant improvement in safety or effectiveness or any supplement that proposes a labeling change pursuant to a report on a pediatric study. A Priority Review designation means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under the Prescription Drug User Fee Act (PDUFA) goals. Under the current PDUFA performance goals, these six- and ten-month review periods are measured from the 60-day filing date rather than the receipt date for NDAs for new molecular entities ("NME"), which typically adds approximately two months to the timeline for review from the date of submission.

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"), that is reasonably likely to predict an effect on IMM irreversible morbidity or mortality or other clinical benefit (i.e., an intermediate clinical endpoint), taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Failure to conduct required post approval studies or confirm a clinical benefit during post marketing studies may lead to the FDA withdrawing the drug from the market. All promotional materials for drug candidates approved under accelerated approval regulations are subject to prior review by the FDA. 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. Further, the Food and Drug Omnibus Reform Act made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

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, organizational commitment to the development and review of the product, including involvement of senior managers. Like Fast Track products, Breakthrough Therapy products are also eligible for rolling review of the NDA. A designation may be rescinded if a product candidate no longer meets the qualifying criteria for breakthrough therapy. A sponsor may also withdraw breakthrough therapy designation if the designation is no longer supported by the emerging data or the drug development program is no longer being pursued.

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.

On January 31, 2022, the Clinical Trials Regulation ("CTR") went into application, which aims to harmonize the submission, assessment and supervision processes for clinical trials in the European Union. The CTR also provided a new Clinical Trials Information System ("CTIS"), which provides a single entry point for sponsors and regulators of clinical trials and a public searchable database for certain clinical trial information.

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.

Moreover, there has recently been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022 (the "Inflation Reduction Act"), which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including certain pharmaceutical companies and the

Pharmaceutical Research and Manufacturers of America have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures, including the prescription drug provisions under the Inflation Reduction Act, as well as other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

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 (the "Board") engages regularly with management on human capital matters. As of December 31, 2023, we had 131 full-time employees, 98 of whom were engaged in research and development activities. We are proud to have a well-balanced and diverse group of employees and believe that our current workforce structure demonstrates our commitment to diversity in all aspects of our business. We note that more than half of our employees as of December 31, 2023, identified as non-Caucasian and more than half as female. We also know that diversity is vital at every level, including the Board. None of our employees are represented by a labor union or covered under a collective bargaining agreement. Due to unfavorable clinical trial results, we have undergone two reorganization plans which significantly decreased our workforce over the past two years. We are mindful of the impact this has on retaining, hiring and motivating employees and have taken various steps to try to mitigate the negative effects of the workforce reductions, including a variety of activities to foster career development, team building, and increased communication throughout the organization. Despite these setbacks, we consider our relationship with our employees to be strong based on engagement scores, employee comments and turnover commensurate with that experienced in our industry.

Company Culture and Employee Development

We continue to build a culture that is both high performing and personally rewarding. We do this by clearly establishing a set of values to guide each of us. We also look for opportunities to recognize employees fostering the culture as a way to reinforce these behaviors. Recognition is a key component in ensuring employee contributions are both seen and appreciated. We have developed several employee recognition programs to support that goal.

We support the growth of our employees through educational programs that enhance technical skills as well as leadership capabilities. We have developed a course for leaders at all levels to hone their skills in key aspects of what teams in today's environment need to thrive. The programs are conducted virtually so employees in all locations can

participate equally. We have also developed an educational grant policy which supports employees in developing the skills relevant to their work at Allakos.

Health, Safety, and Wellness

The health, safety, and wellness of our employees is a priority in which we have always invested. These investments and the prioritization of employee health, safety, and wellness took on particular significance in 2020 and 2021 in light of the COVID-19 pandemic. We provide our employees and their families with access to a variety of innovative, flexible, and convenient health and wellness programs. Program benefits are intended to provide protection and security, so employees can have peace of mind concerning events that may require time away from work or that may impact their financial well-being. Additionally, we provide programs to help support employee physical and mental health by providing tools and resources to help them improve or maintain their health status, encourage engagement in healthy behaviors, and offer choices where possible so they are customized to meet their needs and the needs of their families.

In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, in compliance with government regulations. This included having the vast majority of our employees work from home, while implementing additional safety measures for employees continuing to work on-site. To protect and support our essential team members, we implemented health and safety measures that included providing personal protective equipment ("PPE"), instituting mandatory screening before accessing buildings and implementing protocols to address actual and suspected COVID-19 cases and potential exposure. In 2022, we focused on collecting internal and external insights to inform decision-making on work models that would align with how employees will work in the current environment, including working from home, fully on-site, or in a hybrid fashion, which has evolved as a result of the COVID-19 pandemic. In 2023, our focus was on the implementation and sustained success of the new work models, including on-site engagement activities that reinforce our differentiating culture and facilitate cross-team networking, collaboration, and innovation. We will continue to monitor recommendations from local and national health authorities and respond accordingly.

Compensation and Benefits

We provide compensation and benefits to help meet the needs of our employees. We benchmark our pay annually to ensure it is fair in comparison to local market conditions. In addition to base compensation, our employee programs include annual bonuses, stock incentive awards, an Employee Stock Purchase Plan, 401(k) matching, healthcare insurance benefits, health savings and flexible spending accounts, paid time off and family leave.

Ensuring fair and equitable pay is integral to our commitment to our employees. Our executive team and Board of Directors strongly support this commitment.

January 2024 Reorganization

Due to the clinical trial results released in January 2024, our Board approved a reorganization plan (the "2024 Reorganization Plan") to reduce operating costs and better align our workforce with the new clinical development plans of our business. Under the 2024 Reorganization Plan, our workforce will be reduced by approximately 50% primarily during the first quarter of 2024. The management team and the Board developed severance packages appropriate to the market conditions for similar situations and companies. Impacted employees are eligible to receive severance benefits and Company funded COBRA premiums.

Facilities

Our corporate headquarters are located in San Carlos, California, where we lease approximately 96,000 square feet of office, research and development and laboratory space. The lease term will expire on October 31, 2031. 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 the section entitled "Item 3, *Legal Proceedings*", in this Annual Report on Form 10-K ("Annual Report").

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 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 covering anti-Siglec-6 antibodies, such as AK006, and uses thereof, as of December 31, 2023, contains one U.S. patent application and one pending PCT application. These applications, with projected expiration dates in 2042, are solely owned by us and are drawn to the active component of AK006, an anti-Siglec-6 antibody, pharmaceutical compositions comprising AK006, and methods for treatment of specified diseases using antibodies to Siglec-6.

We have also filed patent applications with claims pending relating to antibodies in preclinical development and methods for treating cancer and immune disorders with these antibodies.

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 ("USPTO") 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 AK006, 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, 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 Section 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.

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, including our financial statements and the related notes and the section entitled "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.
- 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.

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

- Our business may be adversely affected by health epidemics, such as the coronavirus outbreak.
- We are dependent on the success of our lead product candidate, AK006, which is currently in early clinical development. If we are unable to obtain approval for and commercialize AK006 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.
- 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.
- We may face difficulties from changes to current regulations and future legislation.
- Our business may become subject to economic, political, regulatory and other risks associated with international operations directly or indirectly. A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

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, Dr. Adam Tomasi, and our ability to attract and retain other 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 attain commercial success through the sale and marketing of our product candidates that obtain regulatory approval.
- In order to successfully implement our long-term plans and strategies, we will need to increase the number of employees in our organization, and we may experience difficulties in managing this employee 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 AK006, our ongoing clinical trial, 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 scaling-up of manufacturing of AK006, and our third-party manufacturers may be unable to successfully scale-up manufacturing in sufficient quality and quantity for AK006 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.
- Changes in methods of product candidate manufacturing or formulation may result in additional costs, delays or have unintended impacts to the development of our 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.
- We have been and may in the future be subject to securities litigation, which is expensive and could divert management attention from other business concerns.

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.
- Failure to comply with anti-bribery and anti-corruption laws and anti-money laundering laws, and similar laws, could subject us to penalties and other adverse consequences.
- We are subject to various governmental export control and trade sanctions laws and regulations that could impair our ability to compete in international markets or subject us to liability if we violate these controls.
- We may experience disruptions and delays or incur financial damages as a result of system failures or security breaches or incidents.
- The other factors discussed under "Risk Factors".

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 former product candidate. All of our product candidates currently under development, other than AK006, 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. For example, in January 2024, we announced that both our ATLAS clinical trial and our MAVERICK clinical trial failed to meet their primary endpoints. As a result of the results announced in January 2024, we implemented the 2024 Reorganization Plan to better align our resources with our development strategy focused on AK006. 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 $185.7 million and $320.0 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $1,118.5 million. We have devoted substantially all of our resources and efforts to research and development. Our lead product candidate, AK006, is in early 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 our manufacturing and clinical activities, 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. Our ability to develop AK006 and any other product candidates remains uncertain. For example, in January 2024 we announced that both our ATLAS clinical trial and our MAVERICK clinical trial failed to meet their primary endpoints, and in December 2021 we announced that both our ENIGMA study and our KRYPTOS study failed to meet their patient reported symptomatic co-primary endpoints. 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 product candidate, AK006, and any other future product candidates;
- timely receipt of marketing approvals for AK006 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 AK006 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 AK006 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, AK006 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 significant 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 need to reevaluate our operating plan and 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, 2023, we had $170.8 million in cash, cash equivalents and marketable securities. We filed: (i) on August 4, 2022, a prospectus supplement to our shelf registration statement on Form S-3 (File No. 333-265085) that covers the offering, issuance and sale of up to $75.0 million of our common stock from time to time through an "at-the-market" program under the Securities Act of 1933, as amended, and (ii) on September 19, 2022, a prospectus supplement to such shelf registration statement that covered the offering, issuance and sale of 29,882,000 shares of our common stock, at a public offering price of $5.02 per share. We received aggregate net proceeds of $140.6 million, after deducting the underwriting commissions and offering expenses from the September 19, 2022 follow-on offering and as of December 31, 2023 received aggregate net proceeds of $1.0 million under the "at-the-market" program. We believe that our existing cash, cash equivalents and 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 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 marketable securities to fund our development of AK006 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 AK006 and any other product candidates will require a significant amount of capital. Our existing cash, cash equivalents and marketable securities will not be sufficient to fund all of the actions that are necessary to complete the development and commercial approval of AK006 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. Additionally, our ability to raise additional capital may be adversely impacted by potential worsening of global economic conditions and volatility of financial markets in the United States and worldwide. 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, such as the coronavirus outbreak.

The COVID-19 pandemic had an adverse impact on our operations and supply chains and COVID-19, or other health epidemics, may further disrupt our operations, supply chains or those of our contractors, and increase our

expenses. We and our contractors experienced and may 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, the U.S. federal government may, among other things, require domestic industries to provide essential goods and services needed for the national defense, and it used the Defense Production Act in the context of the COVID-19 pandemic to divert supplies and materials to vaccine producers. For example, one of our suppliers informed us that, due to their obligation to prioritize other products or customers pursuant to the Defense Production Act, they were 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 did not cause delays in our overall timeline for clinical trials or regulatory filings, it is possible that similar 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 health epidemics, which could impact our proposed timeline for developing and commercializing AK006 and adversely impact our business, financial condition and results of operations.

In addition, the spread of COVID-19 disrupted the United States' healthcare and healthcare regulatory systems; accordingly, COVID-19 or health epidemics may 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 COVID-19 outbreaks or other health epidemics. Site initiation and patient enrollment may be delayed, for example, due to factors including prioritization of hospital resources toward COVID-19 patients, 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. Health epidemics 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. Health epidemics 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 our operations are impacted from COVID-19 or health epidemics, 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 including COVID-19, could adversely impact our business. Although we are continuing to monitor and assess the effects of public health conditions on our business, the ultimate impact of health epidemics is highly uncertain and subject to change.

We are dependent on the success of our lead product candidate, AK006, which is currently in early clinical development. If we are unable to obtain approval for and commercialize AK006 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 AK006, our lead product candidate. AK006 is in the early-stage of clinical development and we are investing the majority of our efforts and financial resources in the research and development of AK006. Our ability to develop AK006 remains uncertain, especially given that we have not yet completed the Phase 1 trial for AK006. For example, in January 2024, we announced that both our ATLAS clinical trial and our MAVERICK clinical trial with lirentelimab failed to meet their primary endpoints. Similarly, in December 2021, we announced that our phase 3 ENIGMA study and KRYPTOS study failed to meet their patient reported symptomatic co-primary endpoints. AK006 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

AK006 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 AK006 will depend on several factors, including the following:

- initiation and timely completion of our clinical trials of AK006;
- successful and timely enrollment of appropriate patients for the indication(s) included in our current and future clinical trials;
- potential variability of patient-reported measures and outcomes;
- our ability to address any potential delays resulting from factors related to health pandemics;
- obtaining positive data that support demonstration of efficacy, safety and tolerability profiles and durability of effect for our product candidates that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals for AK006 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 for clinical development and, if approved, commercialization of our product candidates;
- 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;
- establishing sales, marketing and distribution capabilities and the successful launch of commercial sales of our product candidates if and when approved for marketing, whether alone or in collaboration with others;
- 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 are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any product candidates from our lead programs, which would materially harm our business. If we do not receive marketing approvals for such product candidates, we may not be able to continue our operations.

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 health epidemics;
- 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. 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 adequately demonstrate safety and efficacy to the satisfaction of regulatory authorities or otherwise produce positive results, which would prevent or delay development, regulatory approval and commercialization.

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 in each target indication. 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. Our product candidates are in an early stage of development, and there is a high risk of failure and we may never succeed in developing marketable products.

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 contract research organizations ("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;
- successful and timely enrollment of appropriate patients for the indication(s) included in our current and future clinical trials;
- potential variability of patient-reported measures and outcomes;
- 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 product candidates approved for sale and we cannot guarantee that we will ever have marketable product candidates. Clinical failure can occur at any stage of clinical development and has been experienced by companies pursuing approval in the indications that we are, or are contemplating, developing. 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 AK006 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 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, including standard of care treatment regimes;
- 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. Intravenous and subcutaneous drugs are less convenient for patients than some other methods of administration, such as an orally delivered drug. The SAD and MAD cohorts in healthy volunteers, as well as well as a cohort in patients with CSU, was administered AK006 via intravenous infusion and we plan to administer AK006 subcutaneously in future clinical trials.

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 AK006 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 AK006 and any other future product candidates may be limited or may not be amenable to treatment with AK006 and

any other products, if and when approved. Even if we obtain significant market share for AK006 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 AK006 into clinical development and through to regulatory approval and commercialization. Our other product candidates are at even earlier stages of development than AK006 and may fail in development or suffer delays that adversely affect their commercial viability.

AK006 is in early clinical development and 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 AK006. 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 product candidates 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 CMS. 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 product does not assure that other payors will also provide coverage for the 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 Siglec-6. The competition we may face with respect to the indications we are targeting with AK006 includes, without limitation, Roche, Novartis, Regeneron, Celldex and Gossamer Bio for CU. 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 AK006 for a limited number of 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 developing AK006 for a limited 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 products or profitable market opportunities. Our spending on current and future research and development activities for specific indications may not yield any commercially viable product candidates. 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, 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.

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. Significant regulatory hurdles remain, both near term and long term, before AK006 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 public health concerns, staffing shortages, government shutdowns and furloughs, or other disruptions to FDA's normal operations. Examples of changes in regulations include future legislation or administrative action, or changes in FDA policy during the period of product development, clinical trial requirements 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.

If 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 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 clinical trial 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 ("GCPs") 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 cGMPs and 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.

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.

In response to the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), in January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

Although we may seek a breakthrough therapy designation for AK006 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 AK006 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.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA") substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. 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. Since the enactment of the ACA, there have been judicial and Congressional challenges to certain aspects of the ACA. 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 will remain in effect through 2032, unless Congress takes additional action.

There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Under the American Rescue Plan Act of 2021, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs was eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures, including the prescription drug provisions under the Inflation Reduction Act, as well as or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and in some cases, designed to encourage importation from other countries and bulk purchasing. For example, FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. Legally mandated price controls on payment amounts by third-party payors or other restrictions on coverage or access could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates that we successfully commercialize or put pressure on our product pricing.

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. Further, if the Supreme Court reverses or curtails the *Chevron* doctrine, which gives deference to regulatory agencies in litigation against FDA and other agencies, more companies may bring lawsuits against FDA to challenge longstanding decisions and policies of FDA, which could undermine FDA's authority, lead to uncertainties in the industry, and disrupt FDA's normal operations, which could delay FDA's review of our marketing applications.

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 used and otherwise processed 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 protected health information governed by the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 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 and Enforcement Act (the "CPRA"), which amends and expands the CCPA, and creates a new California privacy regulatory authority, was passed via ballot initiative in November 2020 and became effective in most material respects on January 1, 2023. Numerous other states have proposed, and in certain cases enacted, new legislation relating to privacy and security. For example, Washington has enacted the My Health, My Data Act, which includes a private right of action. Additionally, numerous other states, including Virginia, Colorado, Utah, Connecticut, Iowa, Indiana, Tennessee, Florida, Texas, Oregon, Delaware, and Montana, have enacted laws addressing privacy and security that impose obligations similar to those of the CCPA and CPRA. More generally, the CCPA and CPRA have prompted proposals for new federal and state privacy legislation that, if enacted, could increase our potential liability, increase our compliance costs, require us to modify our policies and practices, and adversely affect our business.

We may also be subject to or affected by federal, state and foreign laws, regulations and regulatory guidance governing the collection, use, disclosure, security, transfer, storage and other processing 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. We also may be or may be asserted to be subject to additional obligations relating to these matters, including industry standards. The global legislative and regulatory landscapes for privacy, data protection and information security matters continue 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, impose additional costs, and cause it to be necessary or appropriate for us to modify our policies or practices, which we may be unable to do on commercial reasonable terms or at all. 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 (EU 2016/679) (the "GDPR"), and the United Kingdom has adopted its General Data Protection Regulation (the "UK GDPR"), which introduced strict requirements for processing personal data. The GDPR and UK GDPR have increased 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 otherwise process information about them. The processing of sensitive personal data, such as information about health conditions, entails heightened compliance burdens under the GDPR and the UK GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR and the UK GDPR provide 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 under the GDPR (or £17.5 million under the UK GDPR). Numerous other jurisdictions have proposed or enacted legislation that is similar to the GDPR and the UK GDPR. Significant effort and expense are required in order to address the GDPR's and the UK GDPR's restrictions and obligations. Moreover, the requirements under the GDPR and UK 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 or otherwise more burdensome than under current requirements. For example, in July 2020, the Court of Justice of the European Union invalidated the EU-U.S. 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. This has increased the complexity of transferring personal data across borders and may require us to review and amend our mechanisms relating to cross-border data transfer. It is also possible that laws, regulations, and other actual or asserted obligations relating to privacy, data protection or information security may be interpreted and applied in manners that are, or are alleged to be, inconsistent with our practices. Any failure or perceived failure by us to comply with federal, state, or foreign laws, self-regulatory

standards, contractual obligations or other actual or asserted obligations relating to privacy, data protection or cybersecurity could result in negative publicity, harm to our reputation, diversion of management time and effort, proceedings against us by governmental entities or others, and fines, penalties and other liabilities. 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;
- 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 made to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as nurse practitioners and physician assistants, among others), 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.

Our business may become subject to economic, political, regulatory and other risks associated with international operations directly or indirectly. A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

Our business is subject to risks associated with business operations we conduct internationally, as well as indirect impacts from our relationships with collaborators, partners, or contractors who conduct business internationally. We may seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries, including changes in existing regulatory requirements and implementation of new regulatory requirements or policies that impact our clinical development and business operations in foreign countries;
- foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or our interpretation of data from preclinical studies or clinical trials;
- approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- impact of the COVID-19 pandemic or other public health concerns on our ability to produce our product candidates and conduct clinical trials in foreign countries;
- production or supply shortages or other disruptions resulting from any events affecting raw material supply or manufacturing capabilities abroad, including, but not limited to, impacts due to the ongoing

Ukraine-Russia war, addition of certain suppliers or companies to the Unverified List or other export restrictions or sanctions that can impact the supply chain, our business, or business operations of our suppliers, contractors or partners; and

- business interruptions resulting from geo-political actions, national security concerns, trade restrictions, wars, such as the ongoing Ukraine-Russia and Israel-Hamas wars, other regional or geo-political conflicts, and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations. Further, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

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, Dr. Adam Tomasi, and our ability to attract and retain other 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, Dr. Adam Tomasi. If we do not succeed in attracting and retaining other 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 are able to offer. Additionally, we have announced two reorganization plans within the past 24 months, which significantly decreased our workforce. These actions may impact our ability to retain, hire, or motivate employees. 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 attain commercial success through the sale and marketing of 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 and as a result our commercialization efforts may be adversely impacted.

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 long-term plans and strategies, we will need to increase the number of employees in our organization, and we may experience difficulties in managing this employee growth.

In order to successfully implement our long-term 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 AK006 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 AK006 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 business-related activities in order to devote a substantial amount of time to managing these growth activities. In addition, if we reduce our workforce, as we did in the first quarter of 2024 and in early 2022, in order to reduce operating costs or for other reasons, the rate and success at which we can discover, develop and commercialize our product candidates may be limited and the potential for successfully growing our business may be harmed.

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 be assured 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 AK006 and any other future product candidates or otherwise advance our business. We cannot be assured 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 AK006 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, 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 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. 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 trial of AK006, and we expect to continue to rely upon third-parties to conduct additional clinical trials of AK006 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 AK006, our ongoing clinical trial, 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. If we were to experience an unexpected loss of supply of AK006 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 pandemic, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we may 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 and scale, 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 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 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 scaling-up manufacturing of AK006, and our third-party manufacturers may be unable to successfully scale-up manufacturing in sufficient quality and quantity for AK006 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 manufacturers are currently manufacturing AK006 at a scale that is sufficient for us to complete our planned clinical trials.

However, in order to conduct larger clinical trials with AK006 or with any of our other product candidates, we may need to manufacture them in large quantities. Our third-party manufacturers 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, delays or have unintended impacts to the development of our product candidates.

As product candidates progress through preclinical studies and 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 or 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, if approved, 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. If our current manufacturing locations become unavailable at their anticipated capacities or the location of the manufacturing of AK006 or our other product candidates is changed for any reason, 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 $112.87 per share during the fourth quarter of 2021. As of March 8, 2024, the closing price of our common stock was $1.43. 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, 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;
- 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 and ongoing economic uncertainty resulting from the war in Ukraine and conflict in the Middle East, inflationary pressures and rising interest rates. 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.

An impairment in the carrying value of long-lived assets could negatively affect our consolidated results of operations and net worth. We have substantial amounts of long-lived assets, including right-of-use assets, property and equipment, which are subject to impairment analysis and review. Identifying and assessing whether impairment indicators exist, or if events or significant changes in market conditions have occurred, requires significant judgment. Any significant change in market conditions, including a sustained decline in our stock price, that indicate a reduction in carrying value, may give rise to impairment in the period that the change becomes known. We also continually evaluate whether events or circumstances have occurred that indicate the remaining estimated useful lives of our long-lived assets may warrant revision or whether the remaining balance of prepaid or other assets may not be recoverable. Any of the above actions could result in impairment charges which could substantially affect our reported earnings in the periods such charges are recorded.

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 pandemic or other public health concerns;
- 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 AK006 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 AK006 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 AK006 or any of our future product candidates;
- the level of demand for AK006 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 AK006 and any of our future product candidates;
- our ability to commercialize AK006 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 variety of means, including equity offerings and potentially through 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, 2023, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 41.7% 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 have been 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 have been 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 asserted claims for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder and sought damages based on alleged material misrepresentations and omissions concerning our Phase 2 clinical trials of lirentelimab. The complaint, as amended, was dismissed and we consider this matter closed. That said, 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";
- 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 or proceeding asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders;
- any action or proceeding asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or
- any action or proceeding asserting a claim 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.

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.

Failure to comply with anti-bribery and anti-corruption laws and anti-money laundering laws, and similar laws, could subject us to penalties and other adverse consequences.

We have conducted and have ongoing studies in international locations, and may in the future initiate additional studies and conduct other activities in countries other than the U.S. Our business activities are subject to the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201 the UK Bribery Act and other similar anti-bribery or anti-corruption laws and anti-money laundering laws, regulations or rules of other countries in which we operate. Anti-corruption and anti-bribery laws generally prohibit companies, their employees, agents, representatives, business partners, and third-party intermediaries from offering, promising, giving or authorizing others to give improper payments or benefits to recipients in the public or private sector. 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 and compliance procedures designed to prevent violations of anti-corruption and anti-bribery laws.

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 enforcement under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. We sometimes leverage third parties to conduct our business and act on our behalf

outside of the United States. We, our employees, agents, representatives, business partners and third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities and we may be held liable for the corrupt or other illegal activities of these employees, agents, representatives, business partners or third-party intermediaries even if we do not explicitly authorize such activities.

While we have policies and procedures to address compliance with such laws, we cannot assure you that all of our employees, agents, representatives, business parties and third-party intermediaries will comply with our policies and procedures and applicable laws and regulations, particularly given the high level of complexity of these laws.

Any allegations or violations of these laws and regulations could result in whistleblower complaints, investigations, prosecutions, settlements, enforcement actions, fines, severe criminal and civil sanctions, damages, adverse media coverage, loss of export privileges, or suspension or debarment from government contracts all of which 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. Responding to any investigation or action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees.

We are subject to various governmental export control and trade sanctions laws and regulations that could impair our ability to compete in international markets or subject us to liability if we violate these controls.

In some cases, our products are subject to export control laws and regulations, including the Export Administration Regulations administered by the U.S. Department of Commerce, and our activities may be subject to trade and economic sanctions, including those administered by the United States Department of the Treasury's Office of Foreign Assets Control, or OFAC, (collectively, "Trade Controls"). As such, a license may be required to export or re-export our products, or provide related services, to certain countries and end-users, and for certain end-uses. The process for obtaining necessary licenses may be time-consuming or unsuccessful, potentially causing delays in sales or losses of sales opportunities and these licenses may not be issued.

Trade Controls are complex and dynamic regimes and monitoring and ensuring compliance can be challenging. Any failure to comply could subject us to both civil and criminal penalties, including substantial fines, possible incarceration of responsible individuals for willful violations, possible loss of our export or import privileges, and reputational harm. Although we have no knowledge that our activities have resulted in violations of Trade Controls, any failure by us or our partners to comply with applicable laws and regulations would have negative consequences for us, including reputational harm, government investigations, and penalties.

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

We rely on both internal information technology systems and networks, and those of third parties, to transmit, store, and otherwise process information in connection with our business activities. We are increasingly dependent on our technology systems to operate our business, and our ability to effectively manage our business depends on the security, reliability and adequacy of our systems, networks, and data, and those for our CROs and other third-party service providers. Despite the implementation of security measures, the computer systems used by us or our third-party service providers are vulnerable to damage, disruption, outages, and interruptions from computer viruses, ransomware and other malicious code, denial of service and other cyberattacks, supply chain attacks, hacking and other means of obtaining unauthorized access, employee and service provider error or malfeasance, natural disasters, terrorism, war and telecommunication and electrical failure and other means to affect service reliability and threaten data confidentiality, integrity and availability. Any system failure, accident or security breach or incident 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 or incident that leads to the loss, unavailability or corruption 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 affected data. In addition, any disruption or security breach or incident may result in the unavailability or loss of or damage to our data or applications, or inappropriate use, acquisition, disclosure or other processing of confidential or proprietary information and loss of intellectual property. Should any of these occur, 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 or incident could also cause us to incur additional costs to address the disruption, failure, breach or incident and to remedy the damages that arise from such disruption, failure or security breach or incident. We and our third-party service providers may face difficulties or delays in identifying or responding to any disruption, failure, security breach or incident, and may find it necessary or appropriate to incur substantial costs in an effort to improve the protection of our data and information technology infrastructure, whether in response to an actual or suspected security breach or incident or otherwise. Many of our employees work and access systems remotely, which increases the risk of security breaches and incidents. Geopolitical tensions and conflicts, such as the ongoing Russia-Ukraine war may also create heightened risks of cyberattacks and other incidents.

While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, prevent or identify vulnerabilities or security breaches in or incidents impacting our systems or those of our third-party service providers, or prevent or identify other security breaches, incidents, or other compromises or events that lead to the loss or destruction of, or unauthorized access to, or use, disclosure or other processing of data we or our service providers process or maintain. Any actual or perceived security breach or incident may result in claims, demands and proceedings initiated by governmental actors or others, and financial, legal, business and reputational harm to us, including potential fines, penalties, and other damages and liabilities. Any such event may have a material adverse impact on our business, prospects, operating results and financial condition. Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach or incident. 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 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, 2023, we had gross U.S. federal and state net operating loss carryforwards of $893.7 million and $847.2 million, respectively. Federal net operating loss carryforwards of $831.8 million, which were generated after December 31, 2017, do not expire. The remaining $61.8 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 by certain stockholders 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 may have had one or more 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 severely limited or eliminated by an "ownership change" as described above, which could result in increased tax liability to our company or reduced value of our deferred tax assets.

Changes in tax laws or in their implementation or interpretation may adversely affect our financial condition, results of operations, and cash flows.

We are subject to income and non-income taxes in various jurisdictions. Tax laws, regulations and administrative practices in these jurisdictions may be subject to significant change, with or without advance notice. For example, the United States enacted the Tax Cuts and Jobs Act of 2017, which, starting from January 1, 2022, eliminates the option to deduct research and development expenditures currently and instead requires taxpayers to amortize them over five or fifteen years. More recently, the United States enacted the Inflation Reduction Act, which, among other provisions, imposes a one-percent excise tax on certain stock buybacks by U.S. publicly-traded corporations on or after January 1, 2023. In addition, the Organization for Economic Cooperation and Development proposed implementing a global minimum tax of 15%, which is being adopted or considered by many jurisdictions. Changes in tax laws, regulations, or rulings, changes in interpretations of existing laws and regulations, or changes in accounting principles could negatively and materially affect our financial position, cash flows, and results of operations.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we re-design, implement, and maintain reasonable safeguards to minimize identified risks; reasonably address any identified gaps in existing safeguards; and regularly monitor the effectiveness of our safeguards. We devote internal and external resources and designate high-level personnel, including our Chief Financial Officer, who reports to our Chief Executive Officer, to manage the risk assessment and mitigation process.

As part of our overall risk management system, we monitor and test our safeguards and train our employees on these safeguards, in collaboration with human resources, IT, and management. Personnel at all levels and departments are made aware of our cybersecurity policies through trainings.

We engage consultants or other third parties in connection with our risk assessment processes. These service providers assist us to design and implement our cybersecurity policies and procedures, as well as to monitor and test our safeguards.

We have not encountered cybersecurity challenges that have materially impaired our operations or financial standing. For additional information regarding whether any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect our company, including our business strategy, results of operations, or financial condition, please refer to Item 1A, “Risk Factors,” in this Annual Report, including the risk factors entitled “We may experience disruptions and delays or incur financial damages as a result of system failures or security breaches or incidents” and “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".

Governance

One of the key functions of our Board is informed oversight of our risk management process, including risks from cybersecurity threats. Our Board is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our Board administers its cybersecurity risk oversight function directly as a whole, as well as through the audit committee.

Our Chief Financial Officer, in conjunction with our information security team and third-party consultants, is primarily responsible to assess and manage our material risks from cybersecurity threats.

Our Chief Financial Officer oversees our cybersecurity policies and processes, including those described in "Risk Management and Strategy" above. The cybersecurity risk management program includes tools and activities to prevent, detect, and analyze current and emerging cybersecurity threats, and plans and strategies to address threats and incidents.

Our Chief Financial Officer provides briefings to the audit committee regarding our company's cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like. In addition, our Chief Financial Officer provides briefings of any significant cybersecurity matters to the Board as well as an annual update of cybersecurity risks and activities.

Item 2. Properties.

Our corporate headquarters are currently located in San Carlos, California, where we lease approximately 96,000 square feet of office, research and development and laboratory space pursuant to a lease agreement that expires on October 31, 2031.

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 legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

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 March 1, 2024, there were 12 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 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 deems relevant.

Performance Graph

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide this information.

Recent Sales of Unregistered Securities

Not applicable

Use of Proceeds from Registered Securities

Not applicable

Issuer Purchases of Equity Securities

Not applicable

Item 6. [Reserved]

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

You should read the following discussion and analysis 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. 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. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical stage biotechnology company developing therapeutics which target immunomodulatory receptors present on immune effector cells involved in allergic, inflammatory and proliferative diseases. Activating inhibitory receptors allows us to directly target cells involved in disease pathogenesis and, in the setting of allergy and inflammation, has the potential to result in broad inhibition of inflammatory cells. In the setting of proliferative diseases, blocking the inhibitory function of the receptors could restore the immune cells' ability to identify and kill proliferative cells. Our most advanced product candidate, AK006, is currently in a Phase 1 clinical trial.

AK006 has shown activity in preclinical studies including a broad array of animal disease models of mast cell diseases. We have prioritized our AK006 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, operations and finance.

The key elements of our strategy are to:

- ***Evaluate AK006 in healthy volunteers.*** AK006 is currently being evaluated in a Phase 1 SAD and MAD study in healthy volunteers. The study is designed to assess safety, PK and PD of AK006. As part of the phase 1 study, we plan to collect skin biopsies from healthy volunteers dosed with AK006 which will allow us to look at the amount of AK006 that is bound to the Siglec-6 receptor on skin mast cells (also known as the receptor occupancy). Given that CSU is believed to be caused by inappropriately activated skin mast cells, this information will allow us to assess AK006's ability to reach the pathogenic cell type in the target tissue and to determine whether AK006 is achieving receptor occupancy levels consistent with the levels required for inhibition in preclinical studies. We expect to report data from the Phase 1 SAD and MAD portions of the study in the second quarter of 2024.
- ***Obtain POC with AK006 in CSU and other mast cell driven conditions.*** Allakos plans to test AK006 in a randomized, double-blind, placebo-controlled cohort of patients with CSU. We expect data from the CSU cohort to be available at year end 2024. Chronic spontaneous urticaria is an inflammatory skin disease believed to be caused by the inappropriate activation of mast cells in the skin. We believe there is a need for additional treatments for patients with CSU that are refractory to antihistamines. In addition, in 2024 we plan to initiate a clinical study with AK006 in an additional mast cell driven condition.
- ***Develop Subcutaneous formulation of AK006.*** We have also developed a formulation of AK006 for SC administration. As part of the Phase 1 study, we are administering SC AK006 to a cohort of healthy volunteers. We expect to report SC AK006 safety, PK, and PD data, including bioavailability as well as Siglec-6 receptor occupancy in skin biopsy samples, during the third quarter of 2024. Pending positive data from the SC cohort, Allakos plans to use the SC formulation in subsequent AK006 clinical development.
- ***Build therapeutic pipeline.*** Our research is focused on immunomodulatory receptors present on immune effector cells involved in allergic, inflammatory and proliferative diseases. Activating these immunomodulatory receptors allows us to directly target cells involved in disease pathogenesis and, in the setting of allergy and inflammation, has the potential to result in broad inhibition of inflammatory cells. In the setting of proliferative diseases, blocking the inhibitory the function of the receptors could

restore the immune cells' ability to identify and kill proliferative cells. Following this approach, we have developed AK006 and have research programs directed at other immunomodulatory targets.

AK006 targets Siglec-6, an inhibitory receptor expressed selectively on mast cells, a type of white blood cell that is widely distributed in the body and plays a central role in the inflammatory response. Binding of AK006 to Siglec-6 activates the native inhibitory function of the receptor which in turn reduces mast cell activation. In preclinical studies, AK006 inhibited multiple modes of mast cell activation, including IgE, IL-33, KIT, C5a, and MRGPR-X2, resulting in the deep suppression of mast cell activation. In addition to mast cell inhibition, AK006 reduced human tissue mast cells via ADCP in the presence of activated macrophages. AK006 is currently being evaluated in a Phase 1 study in healthy volunteers and Allakos plans to initiate a randomized, double-blind, placebo-controlled cohort of patients with CSU. We expect data from the CSU cohort to be available at year end 2024.

Chronic spontaneous urticaria is an inflammatory skin disease believed to be caused by the inappropriate activation of mast cells via IgE-dependent and IgE-independent pathways in the skin. Symptoms of chronic spontaneous urticaria include frequent and unpredictable eruption of hives, severe itching and swelling. First-line treatment consists of H1 antihistamine medication; however, a significant number of patients do not receive adequate benefit even at up to four times the labeled dose. In the United States, it is estimated that there are 800 thousand adults with moderate-to-severe CSU whose disease is refractory to antihistamines. There is only one FDA approved therapy for patients who are refractory to antihistamines, omalizumab, which binds IgE. Because AK006, inhibits both IgE-dependent and IgE-independent modes of mast cell activation, it has the potential to treat a broad CSU population or show greater symptom improvement.

In the third quarter of 2023 Allakos began dosing healthy volunteers in a randomized, double-blind, placebo-controlled Phase 1 study of AK006. The Phase 1 study of AK006 consists of SAD and MAD cohorts in healthy volunteers as well as well as a cohort in patients with CSU who will be administered AK006 via intravenous infusion. We expect to report SAD and MAD safety, PK and PD results in the second quarter of 2024.

As part of the Phase 1 study, we plan to collect skin biopsies from healthy volunteers dosed with AK006 which will allow us to look at the amount of AK006 that is bound to the Siglec-6 receptor on skin mast cells (also known as the receptor occupancy). Given that CSU is believed to be caused by inappropriately activated skin mast cells, this information will allow us to assess AK006's ability to reach the pathogenic cell type in the target tissue and to confirm that AK006 is achieving receptor occupancy levels consistent with the levels required for inhibition in preclinical experiments. Following the SAD and MAD portions of the Phase 1 AK006 study in healthy volunteers, Allakos plans to initiate a randomized, double-blind, placebo-controlled cohort of patients with CSU. We expect data from the CSU cohort to be available at year end 2024.

We have also developed a formulation of AK006 for SC administration. As part of the Phase 1 study, we are administering SC AK006 to a cohort of healthy volunteers. We expect to report SC AK006 safety, PK, and PD results, including bioavailability as well as Siglec-6 receptor occupancy in skin biopsy samples, during the third quarter of 2024. Pending positive data from the SC cohort, we plan to use the SC formulation in subsequent AK006 clinical development.

We had also been developing lirentelimab (AK002) and, in conjunction with the Phase 2 lirentelimab results in atopic dermatitis and chronic spontaneous urticaria, we announced on January 16, 2024 that we no longer plan to pursue further development of lirentelimab. Lirentelimab has been administered in more than 1,000 patients, and with approximately 500 patients exposed for six months or more. Lirentelimab has generally been well tolerated with no long-term safety findings to date.

Since our inception in 2012, we have devoted substantially all of our resources and efforts towards the research and development of our product candidates. 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 $185.7 million and $320.0 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $1,118.5 million.

In January 2024, we began implementing the 2024 Reorganization Plan to reduce operating costs and better align our workforce with our current clinical development plans of our business. Accordingly, we decided to halt lirentelimab-related activities across clinical, manufacturing, research and administrative functions. As a result, we will reduce our workforce by approximately 50%. While this will result in increased near-term costs, primarily in the first and second quarters of 2024, we believe that the 2024 Reorganization Plan will reduce our overall spending in subsequent quarters subject to periodic fluctuations caused by the timing of ongoing manufacturing development efforts and the timing of future clinical trials. Further, we test long-lived assets for impairment if changes in circumstances or the occurrence of events suggest impairment exists. Any significant change in market conditions, including a sustained decline in our stock price, that indicate a reduction in carrying value may give rise to impairment in the period that the change becomes known. Such factors could result in significant additional non-cash charges including impairment of long-lived assets and accelerated depreciation for assets that have shortened expected asset lives.

As of December 31, 2023, we had cash, cash equivalents and marketable securities of $170.8 million, which we believe will be sufficient to fund our planned operations for at least the next 12 months from the issuance of our audited financial statements included elsewhere in this Annual Report on Form 10-K.

Results of Operations

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

	Year Ended December 31,	
	2023	2022
Operating expenses		
Research and development	$ 150,908	$ 265,081
General and administrative	45,148	57,348
Total operating expenses	196,056	322,429
Loss from operations	(196,056)	(322,429)
Interest income	10,347	3,673
Other income (expense), net	8	(1,196)
Net loss	(185,701)	(319,952)
Unrealized gain (loss) on marketable securities	334	(131)
Comprehensive loss	$ (185,367)	$ (320,083)

Comparison of the Years Ended December 31, 2023 and 2022

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 to conduct nonclinical research and development activities;
- costs incurred under service agreements with clinical contract research organizations (“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, as well as any costs required to cancel any related purchase obligations;
- 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. However, consulting and personnel-related costs, laboratory supplies and non-capital equipment utilized in the conduct of in-house research, in-licensing fees, various pre-clinical research costs 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.

We anticipate that our research and development expenses will fluctuate from quarter-to-quarter in the future, primarily driven by the timing of costs associated with the manufacturing of our product candidates, as well as the timing of future clinical trials. We expect the first half of 2024 to include significant expenses relating to lirentelimab, as we incur closeout costs, employee severance, and other costs resulting from the decision to halt development of lirentelimab.

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

	Year Ended December 31,	
	2023	2022
Contract clinical and manufacturing costs	$ 70,240	$ 181,975
Consulting, professional and personnel-related costs	53,509	56,527
Other unallocated research and development costs	27,159	26,579
Total	$ 150,908	$ 265,081

Research and development expenses were $150.9 million for the year ended December 31, 2023 compared to $265.1 million for the year ended December 31, 2022, a decrease of $114.2 million primarily due to decreases in contract clinical and manufacturing costs.

Contract clinical and manufacturing costs decreased by $111.7 million in fiscal 2023 compared to the prior year largely due to $134.5 million in costs recognized in fiscal 2022 associated with the manufacturing termination agreement entered into during the first quarter of 2022, as well as a decrease of approximately $3.6 million in clinical related costs, offset by a $26.4 million increase in other manufacturing spending.

Consulting, professional and personnel-related costs decreased by $3.0 million in fiscal 2023 compared to the prior year resulting from cost saving measures implemented during the first quarter of 2022 including reduced headcount and offset by a $0.2 million increase in stock-based compensation expense.

Other unallocated research and development costs increased $0.6 million in fiscal 2023 compared to the prior year primarily due to increased pre-clinical research activities.

We anticipate that our research and development expenses will decrease significantly in 2024 due to the cost cutting measures associated with the 2024 Reorganization Plan resulting from our decision to halt lirentelimab development. We believe that the majority of the costs associated with the 2024 Reorganization Plan and lirentelimab close out costs will be incurred during the first half of 2024, but that these cost cutting efforts will reduce our overall spending, excluding stock-based compensation, in subsequent quarters subject to periodic fluctuations caused by the timing of manufacturing development and clinical trial activities.

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.

General and administrative expenses were $45.1 million for the year ended December 31, 2023 compared to $57.3 million for the year ended December 31, 2022, a decrease of $12.2 million. The period-over-period decrease in general and administrative expenses was primarily attributable to cost reduction efforts initiated in the first quarter of 2022 which helped drive an $8.7 million decrease in employee compensation costs as well as a $3.5 million decrease in professional and other administrative expenses. Employee compensation costs in fiscal 2023 included a $2.1 million decrease in stock-based compensation expense as compared to the prior year.

We anticipate that our general and administrative expenses will decrease in 2024 following the employment severance related costs associated with the 2024 Reorganization Plan. We believe that the 2024 Reorganization Plan will reduce our overall spending, excluding stock-based compensation, in subsequent quarters. Additionally, we expect to continue to incur costs associated with operating 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, information technology and facility activities, and other ancillary administrative and professional services.

Interest Income

Interest income was $10.3 million for the year ended December 31, 2023, compared to $3.7 million for the year ended December 31, 2022, an increase of $6.7 million. The year-over-year increase is primarily attributable to higher interest rates.

Other Income (Expense), Net

Other income, net, for the year ended December 31, 2023 was immaterial, compared to a $1.2 million loss for the year ended December 31, 2022, primarily due to foreign exchange losses incurred in fiscal 2022.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2023, we had cash, cash equivalents and marketable securities of $170.8 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 audited financial statements included elsewhere in this Annual Report on Form 10-K.

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 primarily through equity offerings.

In May 2022, we filed a shelf registration statement on Form S-3 (File No. 3333-265085) with the SEC pursuant to which we may, from time to time, sell up to an aggregate of $250.0 million of our common stock. On May 31, 2022, the registration statement was declared effective by the SEC, which allows us to access the capital markets for the three-year period following this effective date. Our September 2022 equity offering and our outstanding "at-the-market" offering program were offered under this Form S-3. Further details of these programs are included below.

Additionally, in November 2023, we filed a shelf registration statement on Form S-3 (File No. 333-275517) with the SEC pursuant to which we may, from time to time, sell up to an aggregate of $250.0 million of our common stock. On November 24, 2023, the registration statement was declared effective by the SEC, which allows us to access the capital markets for the three-year period following this effective date.

September 2022 Offering

On September 21, 2022, we closed an underwritten registered direct offering (the "September 2022 Offering") under our shelf registration statement on Form S-3 (File No. 333-265085) pursuant to which we sold an aggregate of 29,882,000 shares of our common stock at an offering price of $5.02 per share. We received aggregate net proceeds of $140.6 million, after deducting the underwriting commissions and offering expenses.

"At-the-Market" Equity Offerings

On August 4, 2022, we entered into a sales agreement (the "2022 Sales Agreement") with Cowen and Company, LLC ("Cowen"). Pursuant to the 2022 Sales Agreement we may sell, from time to time up to an aggregate of $75.0 million in gross sales proceeds of our common stock through an "at-the-market" offering ("ATM Offering"). We will pay Cowen a commission equal to 3.0% of the gross proceeds from the sale of shares of our common stock under the 2022 Sales Agreement. The $75.0 million of common stock that may be offered, issued and sold in the ATM Offering is included in the $250.0 million of securities that may be offered, issued and sold by us under our registration statement on Form S-3 (File No. 333-265085). We expect to use the net proceeds from sales under the 2022 Sales Agreement for general corporate purposes.

During the year ended December 31, 2023, we sold 0.1 million shares of our common stock at an average price of $7.20 per share through our ATM Offering, resulting in proceeds of $1.0 million net of commissions, with all sales occurring during the first quarter of 2023. Under our current ATM Offering program, $74.0 million of common stock remain available for future sales as of December 31, 2023; however, we are not obligated to make any sales under this program.

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,	
	2023	2022
Net cash used in operating activities	$ (116,480)	$ (279,971)
Net cash provided by investing activities	93,175	71,681
Net cash provided by financing activities	2,528	141,882
Net decrease in cash, cash equivalents and restricted cash	$ (20,777)	$ (66,408)

Comparison of the Years Ended December 31, 2023 and 2022

Cash Used in Operating Activities

Net cash used in operating activities was $116.5 million for the year ended December 31, 2023, which was primarily attributed to our net loss of $185.7 million adjusted for net noncash charges of $43.6 million and net changes in operating assets and liabilities of $25.6 million. Noncash charges included $41.2 million in stock-based compensation expense, $6.1 million in depreciation and amortization expense, $1.5 million in noncash lease expense and were offset by $5.3 million in net accretion of premium and discounts on marketable securities.

Net cash used in operating activities was $280.0 million for the year ended December 31, 2022, which was primarily attributable to our net loss of $320.0 million adjusted for net noncash charges of $53.7 million and net changes in operating assets and liabilities of $13.8 million. Noncash charges included $43.2 million in stock-based compensation expense, $7.1 million in depreciation and amortization expense, $2.9 million in noncash lease expense and $0.6 million in net amortization of premium and discounts on marketable securities.

Cash Provided by Investing Activities

Net cash provided by investing activities was $93.2 million for the year ended December 31, 2023, which consisted of $263.0 million in proceeds from maturities of marketable securities, partially offset by $169.2 million in purchases of marketable securities and $0.6 million in purchases of property and equipment.

Net cash provided by investing activities was $71.7 million for the year ended December 31, 2022, which consisted of $287.0 million in proceeds from maturities of marketable securities, $20.0 million in proceeds from the sale of marketable securities and $1.2 million in proceeds from the sale of property and equipment, partially offset by $228.1 million in purchases of marketable securities and $8.3 million in purchases of property and equipment.

Cash Provided by Financing Activities

Net cash provided by financing activities was $2.5 million for the year ended December 31, 2023, which consisted primarily of $1.0 million in proceeds from the issuance of common stock under our ATM Offering program, $0.9 million in proceeds from the issuance of common stock under the 2018 ESPP and $0.7 million in proceeds from employees for the exercise of stock options.

Net cash provided by financing activities was $141.9 million for the year ended December 31, 2022, which consisted primarily of $140.6 million in proceeds from the issuance of common stock pursuant to the September 2022 Offering, $0.9 million in proceeds from employees for the exercise of stock options and $0.4 million in proceeds from the issuance of common stock under the 2018 ESPP.

Funding Requirements

As of December 31, 2023, we had cash, cash equivalents and marketable securities, excluding restricted cash, of $170.8 million, which we believe will be sufficient to fund our planned operations for at least the next 12 months from the issuance date of our audited financial statements included elsewhere in this Annual Report on Form 10-K. We will continue to require additional capital to develop our product candidates, achieve commercial approval and fund operations for the foreseeable future. We intend to seek and have sought to raise funding from time to time

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 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, and if successful, the cost and time necessary to bring product candidates to market;
- 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 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, 2023 (in millions) and does not incorporate any cancellations or termination agreements entered into subsequent to December 31, 2023:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations [1]	$ 61.8	$ 7.4	$ 14.8	$ 15.7	$ 23.9
Purchase obligations [2]	6.0	6.0	—	—	—
Total	$ 67.8	$ 13.4	$ 14.8	$ 15.7	$ 23.9

(1) Operating lease obligations represent future lease payments due primarily under our corporate facility lease agreement.

(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.

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

We account for our leases in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 842, "Leases" ("ASC 842"). 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.

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.

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.

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.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development contracts. We do not believe that inflation has had a material effect on our financial results during the periods presented.

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

Basis for Opinion

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

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

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

Critical Audit Matter

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

Accrued Clinical Investigative Sites Expenses

Description of the Matter	As discussed in Note 2, accrued research and development expenses are recorded for estimated unpaid costs of research and development activities conducted by the Company and its third-party service providers, which include the conduct of preclinical and clinical studies, and contract manufacturing activities. Accrued contract research and development expenses were $22.3 million as of December 31, 2023, which includes the estimated accrued clinical investigative sites expenses incurred but not invoiced under agreements with investigative clinical trial sites that conduct clinical studies ("Accrued Clinical Investigative Sites Expenses"). The accrual for these Accrued Clinical Investigative Site Expenses includes estimates of services completed. Auditing these Accrued Clinical Investigative Sites Expenses was complex due to the required analysis of extensive data in determining the estimated expenses incurred but not invoiced.
How We Addressed the Matter in Our Audit	We obtained an understanding of the Company's process to determine Accrued Clinical Investigative Sites Expenses. Our audit procedures included testing the accuracy and completeness of the inputs used in management's analysis to determine expenses incurred but not invoiced and making direct inquiries of the Company's personnel that oversee the clinical trials. Further, we verified the accrued expenses incurred but not invoiced to the underlying agreements and the information provided by third-party service providers.

/s/ Ernst & Young LLP

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

San Mateo, California

March 14, 2024

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

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 66,440	$ 87,217
Investments	104,354	192,569
Prepaid expenses and other current assets	9,095	29,057
Total current assets	179,889	308,843
Property and equipment, net	33,369	39,144
Operating lease right-of-use assets	24,136	30,225
Other long-term assets	6,216	8,208
Total assets	$ 243,610	$ 386,420
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,764	$ 4,832
Accrued expenses and other current liabilities	34,814	25,206
Total current liabilities	36,578	30,038
Operating lease liabilities, net of current portion	38,215	45,949
Total liabilities	74,793	75,987
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 20,000 shares authorized as of December 31, 2023 and 2022; no shares issued and outstanding as of December 31, 2023 and 2022	—	—
Common stock, $0.001 par value per share; 200,000 shares authorized as of December 31, 2023 and 2022; 87,750 and 85,387 shares issued and outstanding as of December 31, 2023 and 2022, respectively	88	85
Additional paid-in capital	1,287,156	1,243,408
Accumulated other comprehensive income (loss)	50	(284)
Accumulated deficit	(1,118,477)	(932,776)
Total stockholders' equity	168,817	310,433
Total liabilities and stockholders' equity	$ 243,610	$ 386,420

See accompanying notes to financial statements

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

	Year Ended December 31,	
	2023	2022
Operating expenses		
Research and development	$ 150,908	$ 265,081
General and administrative	45,148	57,348
Total operating expenses	196,056	322,429
Loss from operations	(196,056)	(322,429)
Interest income	10,347	3,673
Other income (expense), net	8	(1,196)
Net loss	(185,701)	(319,952)
Unrealized gain (loss) on marketable securities	334	(131)
Comprehensive loss	$ (185,367)	$ (320,083)
Net loss per common share:		
Basic and diluted	$ (2.14)	$ (5.06)
Weighted-average number of common shares outstanding:		
Basic and diluted	86,798	63,284

See accompanying notes to financial statements

ALLAKOS INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2021	54,622	$ 54	$ 1,058,399	$ (153)	$ (612,824)	$ 445,476
Stock-based compensation expense	—	—	43,158	—	—	43,158
Issuance of common stock upon exercise of stock options	464	1	852	—	—	853
Issuance of common stock upon 2018 ESPP purchase	104	—	438	—	—	438
Issuance of common stock upon follow-on offering, net of offering costs of $9,417	29,882	30	140,561	—	—	140,591
Issuance of common stock upon vesting of restricted stock units	315	—	—	—	—	—
Unrealized gain (loss) on marketable securities	—	—	—	(131)	—	(131)
Net loss	—	—	—	—	(319,952)	(319,952)
Balance as of December 31, 2022	85,387	$ 85	$ 1,243,408	$ (284)	$ (932,776)	$ 310,433
Stock-based compensation expense	—	—	41,223	—	—	41,223
Issuance of common stock upon exercise of stock options	206	—	673	—	—	673
Issuance of common stock upon 2018 ESPP purchase	281	—	865	—	—	865
Issuance of common stock upon ATM offering	142	—	990	—	—	990
Issuance of common stock upon vesting of restricted stock units	1,734	3	(3)	—	—	—
Unrealized gain (loss) on marketable securities	—	—	—	334	—	334
Net loss	—	—	—	—	(185,701)	(185,701)
Balance as of December 31, 2023	87,750	$ 88	$ 1,287,156	$ 50	$ (1,118,477)	$ 168,817

See accompanying notes to financial statements

ALLAKOS INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (185,701)	$ (319,952)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	41,223	43,158
Net amortization (accretion) of premiums and discounts on marketable securities	(5,250)	588
Depreciation and amortization	6,141	7,071
Noncash lease expense	1,491	2,904
Gain on lease modification	—	—
Loss on disposal of property and equipment	3	28
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	19,994	(2,431)
Other long-term assets	1,992	(574)
Accounts payable	(2,845)	(8,765)
Accrued expenses and other current liabilities	9,907	1,152
Operating lease liabilities, net of current portion	(3,435)	(3,150)
Net cash used in operating activities	(116,480)	(279,971)
Cash flows from investing activities		
Purchases of marketable securities	(169,233)	(228,144)
Proceeds from maturities of marketable securities	263,000	287,000
Proceeds from sale of marketable securities	—	19,989
Purchases of property and equipment	(592)	(8,333)
Proceeds from sale of property and equipment	—	1,169
Net cash provided by investing activities	93,175	71,681
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	990	140,591
Proceeds from exercise of stock options, net of repurchases	673	853
Proceeds from issuance of common stock under 2018 ESPP	865	438
Net cash provided by financing activities	2,528	141,882
Net increase (decrease) in cash, cash equivalents and restricted cash	(20,777)	(66,408)
Cash, cash equivalents and restricted cash, beginning of period	88,689	155,097
Cash, cash equivalents and restricted cash, end of period	$ 67,912	$ 88,689
Supplemental disclosures		
Right-of-use assets obtained in exchange for lease obligations	$ 665	$ 1,422
Noncash adjustments to right-of-use assets	$ (5,307)	$ —
Changes of property and equipment in accounts payable and accruals	$ (223)	$ (4,021)

See accompanying notes to financial statements

ALLAKOS INC.
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 developing therapeutics which target immunomodulatory receptors present on immune effector cells involved in allergic, inflammatory and proliferative diseases. Our most advanced product candidate is AK006 which targets mast cells. Inappropriately activated mast cells have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. 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 San Carlos, California.

Liquidity Matters

Since inception, the Company has incurred net losses and negative cash flows from operations. During the year ended December 31, 2023, the Company incurred a net loss of $185.7 million and used $116.5 million of cash in operations. As of December 31, 2023, the Company had an accumulated deficit of $1,118.5 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.

Due to the clinical study results released in January 2024, our Board of Directors approved a reorganization plan to reduce operating costs and better align our workforce with our current clinical development plans of our business (the "2024 Reorganization Plan"). Refer to Note 12 "Subsequent Events" for additional details.

The Company had $170.8 million of cash, cash equivalents and marketable securities at December 31, 2023. 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 stock-based compensation expense, accrued research and development expense, and lease related assets and liabilities. 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,	
	2023	2022
Cash and cash equivalents	$ 66,440	$ 87,217
Restricted cash in other long-term assets	1,472	1,472
Total	$ 67,912	$ 88,689

Restricted cash at December 31, 2023 represents $1.5 million of security deposits for the lease of the Company's facility in San Carlos, California. The security deposit is in the form of a letter of credit secured by restricted cash and is recorded in other long-term assets on the Company's balance sheets.

Investments

The Company invests in marketable securities, primarily securities issued by the U.S. government and its agencies. The Company's investments 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 (loss). 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 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. Generally, the useful lives of laboratory equipment and capitalized software are five years, furniture and office equipment are three to five years, and leasehold improvements property and equipment are the shorter of the remaining lease term or the estimated life of the assets.

Any resulting gains or losses on dispositions of property and equipment are included as a component of other income (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

The Company accounts for its leases in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 842, "Leases" ("ASC 842"). 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.

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 or other long-term assets, as appropriate, 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. Costs to terminate commitments with third-party suppliers performing research and development activities and 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 or other long-term assets, as appropriate. 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 our stock as well as 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.

The Company recognizes the stock-based compensation expense related to performance-based stock awards or performance-based RSUs ("PSUs") if the performance targets are deemed probable of being achieved. The vesting of PSUs requires that certain performance conditions are achieved during the performance period and is subject to the employee’s continued service requirements.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Current income tax expense or benefit represents the amount of income taxes the Company expects to pay or have refunded in the current year. The Company’s 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 it measures using the enacted tax rates and laws that will be in effect when such items are expected to reverse. The Company reduces deferred income tax assets, as necessary, by applying a valuation allowance to the extent that it determined it is more likely than not that some or all of our tax benefits will not be realized.

The Company accounts for uncertain tax positions in accordance with ASC 740-10, Accounting for Uncertainty in Income Taxes. The Company assesses 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 its positions, the Company measures the largest amount of benefit possessing greater than fifty percent likelihood of being realized upon ultimate settlement. The Company reassesses 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.

Comprehensive Loss

Comprehensive loss is defined as the change in stockholders’ equity 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, 2023 and 2022 are a result of unrealized gains and losses on the Company’s investments in marketable securities included in current assets on the Company's 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.

The Company’s weighted-average shares of common stock outstanding increased from 63.3 million shares of common stock outstanding during the year ended December 31, 2022 to 86.8 million shares of common stock outstanding during the year ended December 31, 2023 primarily as a result of the 29.9 million shares sold as part of an underwritten registered direct offering closed on September 21, 2022 (the “September 2022 Offering”). Refer to Note 8 “Stockholders’ Equity” for additional details related to the offering.

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

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss	$ (185,701)	$ (319,952)
Denominator:		
Weighted-average shares of common stock outstanding, basic and diluted	86,798	63,284
Net loss per share, basic and diluted	$ (2.14)	$ (5.06)

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,	
	2023	2022
Options to purchase common stock	7,968	5,423
Unvested restricted stock units	5,621	4,478
Unvested performance stock unit	2,845	3,276
Shares issuable under employee stock purchase plans	127	135
Total	16,561	13,312

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 Issued and Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This ASU requires entities to expand its existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. This authoritative guidance will be effective for us in fiscal year 2025, with early adoption permitted. The Company is currently evaluating the impact of the ASU, but does not expect any material impacts upon adoption.

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, 2023			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 67,070	$ —	$ —	$ 67,070
Total cash equivalents	67,070	—	—	67,070
Short-term marketable securities				
U.S. treasuries	96,705	—	—	96,705
U.S. government agency bonds	7,649	—	—	7,649
Total short-term marketable securities	104,354	—	—	104,354
Total cash equivalents and short-term marketable securities	$ 171,424	$ —	$ —	$ 171,424

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 86,270	$ —	$ —	$ 86,270
Total cash equivalents	86,270	—	—	86,270
Short-term marketable securities				
U.S. treasuries	192,569	—	—	192,569
Total short-term marketable securities	192,569	—	—	192,569
Total cash equivalents and short-term marketable securities	$ 278,839	$ —	$ —	$ 278,839

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, 2023 and 2022.

4. Investments

All investments were considered available-for-sale at December 31, 2023 and 2022. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's investments by major security type are summarized in the table below (in thousands):

	December 31, 2023			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale securities				
U.S. treasuries classified as investments	$ 96,688	$ 39	$ (22)	$ 96,705
U.S. government agency bonds	7,652	—	(3)	7,649
Total available-for-sale securities	$ 104,340	$ 39	$ (25)	$ 104,354

	December 31, 2022			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale securities				
U.S. treasuries classified as investments	$ 192,853	$ 3	$ (287)	$ 192,569
Total available-for-sale securities	$ 192,853	$ 3	$ (287)	$ 192,569

The amortized cost of available-for-sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. As of December 31, 2023 and 2022, the aggregate fair value of securities held by the Company in an unrealized loss position for less than twelve months was $53.7 million and $162.6 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, 2023 and 2022.

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, 2023 and 2022, 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

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2023	2022
Prepaid clinical expenses	$ 1,092	$ 1,741
Prepaid manufacturing expenses	3,877	21,998
Other prepaid expenses or current assets	4,126	5,318
Total	$ 9,095	$ 29,057

The decrease in prepaid manufacturing expenses from December 31, 2022 to December 31, 2023 is primarily due to the timing of manufacturing activities relating to lirentelimab.

Property and Equipment, Net

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

	December 31,	
	2023	2022
Laboratory equipment	$ 6,993	$ 6,473
Furniture and office equipment	3,947	3,947
Leasehold improvements	32,386	32,457
Capitalized software	4,382	4,112
Construction-in-progress or pending installation	69	422
	47,777	47,411
Less accumulated depreciation	(14,408)	(8,267)
Property and equipment, net	$ 33,369	$ 39,144

Depreciation expense for the years ended December 31, 2023 and 2022 was $6.1 million, and $7.1 million, respectively. During the year ended December 31, 2022, gross fixed assets of $5.8 million with accumulated depreciation of $4.6 million were disposed of or sold for $1.2 million in conjunction with exiting the Redwood City facility.

Other Long-Term Assets

Other long-term assets were $6.2 million and $8.2 million as of December 31, 2023 and 2022, respectively. Other long-term assets at December 31, 2023 and 2022 included $0.8 million and $6.6 million, respectively, in advance payments to CDMOs for development and manufacturing services expected to be provided more than one year from the balance sheet date. Other long-term assets as of December 31, 2023 additionally includes $3.9 million of tax credit receivables classified as long-term.

Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2023	2022
Accrued contract research and development expense	$ 22,262	$ 13,950
Accrued compensation and benefits expense	8,674	7,039
Current portion of operating lease liabilities	3,250	3,161
Other current liabilities	628	1,056
Total	$ 34,814	$ 25,206

6. Leases

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.

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 from August 2021 until October 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 of up to $14.4 million, which was fully utilized and are recorded in lease obligations.

On March 27, 2023, the Company entered into an amendment for the 2019 San Carlos Lease, whereby rentable square feet was adjusted to 95,692 square feet and lease payments were reduced by approximately 2.5% per month, effective from January 1, 2022 through the end of the lease term. The Company accounted for these changes as a modification under ASC 842 and the operating right-of-use asset and lease liability were remeasured during the first quarter of 2023 utilizing an estimated incremental borrowing rate of 10.5%. Our estimated incremental borrowing rate was based on our estimated rate of interest for a fully collateralized borrowing over a similar term as the remaining lease payments while incorporating our credit risk. As a result of the modification, the right-of-use asset and lease liability decreased by approximately $5.6 million. No gain or loss was recognized upon the modification.

Classification of Operating Leases

The 2019 San Carlos Lease required security deposits of $1.5 million, which the Company satisfied by establishing letters of credit secured by restricted cash. As of December 31, 2023 and 2022, a security deposit of $1.5 million for the 2019 San Carlos Lease was recorded as restricted cash 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, 2023 and 2022 was as follows (in thousands):

	December 31,	
	2023	2022
Operating lease liabilities		
Current portion included in accrued expenses and other current liabilities	$ 3,250	$ 3,161
Operating lease liabilities, net of current portion	38,215	45,949
Total operating lease liabilities	$ 41,465	$ 49,110

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,	
	2023	2022
Operating lease costs	$ 5,806	$ 5,886
Variable costs	3,627	3,007
Total lease costs	$ 9,433	$ 8,893

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

Cash paid for 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 $6.7 million and $6.8 million for the years ended December 31, 2023 and 2022.

Cash received for amounts related to tenant improvement allowances from lessors was $0.3 million and $1.3 million for the years ended December 31, 2023 and 2022, respectively.

Operating Lease Obligations

Future lease payments required under operating leases included on the Company's balance sheet at December 31, 2023 are as follows (in thousands):

Fiscal Year Ending December 31,		
2024	$	7,441
2025		7,287
2026		7,506
2027		7,731
2028		7,963
Thereafter		23,871
Total future lease payments		61,799
Less:		
Present value adjustment		20,334
Operating lease liabilities	$	41,465

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, 2023, the weighted-average remaining lease term of the Company's leases was 7.8 years and the weighted-average discount rate used to determine the operating lease liabilities included on the balance sheet was 10.5%.

As of December 31, 2023, the Company has not been party to any lease agreements containing material residual value guarantees or material restrictive covenants.

7. Commitments and Contingencies

As of December 31, 2023, the Company's commitments include an estimated $6.0 million of noncancellable purchase commitments, including commitments with contract manufacturers for which the Company has not received the goods or services.

Additionally, the Company enters 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, the Company would only be obligated for services received as of the effective date of the termination, along with cancellation fees, as applicable.

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, 2023.

8. Stockholders' Equity

September 2022 Offering

On September 21, 2022, the Company closed an underwritten registered direct offering (the "September 2022 Offering") under its shelf registration statement on Form S-3 (File No. 333-265085), supplemented by a prospectus supplement filed with the SEC on September 19, 2022 pursuant to Rule 424(b) under the Securities Act of 1933, as amended. In connection with the September 2022 Offering, the Company sold an aggregate of 29,882,000 shares of our common stock, par value $0.001 per share, at an offering price of $5.02 per share. Aggregate net proceeds were approximately $140.6 million, after deducting the underwriting commissions and estimated offering expenses.

"At-the-Market" Equity Offerings

On August 4, 2022, the Company entered into a sales agreement (the "2022 Sales Agreement") with Cowen and Company, LLC ("Cowen"). Pursuant to Sales Agreement, the Company may sell, from time to time, up to an aggregate of $75.0 million in gross sales proceeds of its common stock through an "at-the-market" offering ("ATM Offering") as defined under the Securities Act of 1933. The Company will pay a commission equal to 3% of the gross proceeds from the sale of shares of its common stock under the Sales Agreement. The $75.0 million of common stock that may be offered, issued and sold in the ATM Offering is included in the $250.0 million of securities that may be offered, issued and sold by the Company under its registration statement on Form S-3 (File No. 333-265085). The Company expects to use the net proceeds from sales under the 2022 Sales Agreement for general corporate purposes.

During the year ended December 31, 2023, the Company sold 0.1 million shares of its common stock at an average price of $7.20 per share through its ATM Offering, resulting in proceeds of $1.0 million net of commissions, with all sales occurring during the first quarter of 2023. Under its current ATM Offering program, $74.0 million of common stock remain available for future sales as of December 31, 2023; however, the Company is not obligated to make any sales under this program.

9. Stock-Based Compensation

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

	Year Ended December 31,	
	2023	2022
Research and development	$ 17,599	$ 17,399
General and administrative	23,624	25,759
Total	$ 41,223	$ 43,158

No income tax benefits for stock-based compensation expense have been recognized for the years ended December 31, 2023 and 2022, 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, performance-based awards ("PSUs") and other stock-based awards. 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, 2023, the maximum number of shares that may be added to the 2018 Plan pursuant to the preceding clause is 2,546,977 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.

As of December 31, 2023, the number of shares available for issuance under the 2018 Plan was 2,036,811.

Stock Options

Stock option activity under the 2018 Plan and the 2012 Plan during the year ended December 31, 2023 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, 2022	5,423	$ 15.41	6.4	$ 22,657
Granted	3,458	$ 5.79		
Exercised	(206)	$ 3.26		
Expired	(267)	$ 48.35		
Forfeited	(440)	$ 7.99		
Balance at December 31, 2023	7,968	$ 10.85	6.9	$ 3,168
Options exercisable	4,216	$ 13.62	5.0	$ 3,165
Options vested and expected to vest	7,776	$ 10.95	6.9	$ 3,168

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

	Year Ended December 31,	
	2023	2022
Risk-free interest rate	3.88%	2.95%
Expected volatility	99.96%	75.94%
Expected dividend yield	—	—
Expected term (in years)	5.96	5.84

The weighted-average fair value of options granted during the years ended December 31, 2023 and 2022 was $4.61 and $2.76 per share, respectively.

The aggregate fair value of stock options that vested during the years ended December 31, 2023 and 2022 was $6.7 million and $15.2 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. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2023 and 2022 was $0.1 million and $1.8 million, respectively.

As of December 31, 2023, total unrecognized stock-based compensation expense relating to unvested stock options was $16.9 million. This amount is expected to be recognized over a weighted-average period of 2.4 years.

Time-based Restricted Stock Units

Each time-based restricted stock unit ("RSU") represents one equivalent share of our common stock to be awarded after satisfying the applicable continued service-based vesting criteria over a specified period. The fair value for these RSUs is based on the closing price of our common stock on the date of grant. The RSUs do not entitle

participants to the rights of holders of common stock, such as voting rights, until the shares are issued. RSUs that are expected to vest are net of estimated future forfeitures.

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, 2022	4,478	$ 16.90
Granted	3,860	$ 6.52
Vested	(1,734)	$ 18.29
Forfeited	(983)	$ 12.23
Balance at December 31, 2023	5,621	$ 10.16

The weighted-average fair value of RSUs granted during the years ended December 31, 2023 and 2022 was $6.52 and $5.38, respectively.

As of December 31, 2023, total unrecognized stock-based compensation expense relating to unvested RSUs was $48.4 million and the weighted-average remaining vesting period was 2.3 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, 2023. As of December 31, 2023, the aggregate intrinsic value of RSUs was $15.3 million.

Performance-based Restricted Stock Units

During the year ended December 31, 2023, no restricted stock units with performance-based vesting ("PSUs") from the 2018 Plan were granted, however, 2.8 million PSUs were outstanding as of December 31, 2023. Each PSU represents one equivalent share of our common stock to be awarded upon vesting at the end of the performance periods, if specific performance goals set by the Board of Directors are achieved. No PSUs will vest if the performance goals are not met. The fair value of these PSUs is based on the closing price of our common stock on the date of grant. The Company assesses the probability of achieving the performance goals on a quarterly basis. Changes in our assessment of the probability results in adjustments to stock-based compensation, which may include either a cumulative catch-up of expense or a reduction of expense depending on whether the likelihood of vesting has increased or decreased, that is recognized in the period such determination is made. The PSUs do not entitle participants to the rights of holders of common stock, such as voting rights, until the shares are issued. PSUs that are expected to vest are net of estimated future forfeitures.

The following table summarizes the PSUs activity for the year ended December 31, 2023 (in thousands, except per share data):

	Number of Shares	Weighted-Average Grant Date Fair Value
Balance at December 31, 2022	3,276	$ 6.21
Granted	—	$ —
Forfeited	(431)	$ 5.58
Balance at December 31, 2023	2,845	$ 6.30

No stock-based compensation expense related to the PSUs has been recognized during the years ended December 31, 2023 and 2022 as the achievement of the performance conditions were not deemed probable and the remaining vesting period is undeterminable. As of December 31, 2023, total unrecognized compensation expense relating to PSUs was $17.9 million and the aggregate intrinsic value of PSUs at December 31, 2023 was $7.8 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"). 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. As of December 31, 2023, the number of shares available for issuance under the 2018 ESPP was 2,781,902.

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 years ended December 31, 2023 and 2022, stock-based compensation related to the 2018 ESPP was $0.8 million and $0.8 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,	
	2023	2022
Risk-free interest rate	5.14%	2.20%
Expected volatility	127.37%	75.83%
Expected dividend yield	—	—
Expected term (in years)	1.32	1.67

As of December 31, 2023, total unrecognized compensation expense relating to shares to be purchased under the 2018 ESPP was $0.3 million and the weighted-average remaining vesting period was 1.1 years.

10. Income Taxes

The Company is subject to income taxes in the United States and certain states in which it operates, and it uses estimates in determining its provisions for income taxes. Significant management judgement is required in determining the Company's provision for income taxes, deferred tax assets and liabilities and valuation allowances recorded against net deferred tax assets in accordance with U.S. GAAP. These estimates and judgements occur in the calculation of tax credits, benefits, and deductions, and in the calculation of certain tax assets and liabilities, which arise from certain temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant changes to these estimates may result in an increase or decrease to the Company's tax provision in the current or subsequent period.

The Internal Revenue Code of 1986, as amended (the "Code"), provides for a limitation of the annual use of net operating losses ("NOLs") 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. The Company may have had one or more ownership changes in the past, and it may experience ownership changes in the future. Accordingly, the Company's ability to utilize its NOLs and certain other tax attributes could be severely limited or eliminated.

Total deferred income tax assets, net of valuation allowance, at December 31, 2023 and 2022 were as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets		
Net operating loss carryforwards	$ 247,208	$ 225,924
Capitalized research expenditures	65,677	48,767
Research and development credits	42,347	35,906
Accruals and reserves	8,182	6,839
Stock-based compensation	5,519	6,341
Lease liability	11,314	13,403
Fixed and intangible assets	295	—
Gross deferred tax assets	380,542	337,180
Less: valuation allowance	(373,957)	(328,553)
Deferred tax assets, net of valuation allowance	6,585	8,627
Deferred tax liabilities		
Fixed and intangible assets	—	378
Right-of-use asset	6,585	8,249
Gross deferred tax liabilities	6,585	8,627
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 $374.0 million and $328.6 million has been established at December 31, 2023 and 2022, respectively. The change in the valuation allowance was $45.4 million and $125.0 million for the years ended December 31, 2023 and 2022, respectively. The Company has incurred NOL since inception. As of December 31, 2023, the Company had federal and state NOL carryforwards of $893.7 million and $847.2 million, respectively. Federal NOL carryforwards of $831.8 million, which were generated after December 31, 2017, do not expire. The remaining $61.8 million of Federal NOL carryforwards expire beginning in 2032. As of December 31, 2023, the Company had federal and California research and other tax credit carryforwards of $48.1 million and $11.2 million, respectively. The federal tax credits expire beginning in 2033. The California tax credits can be carried forward indefinitely.

In accordance with the Tax Cuts and Jobs Act of 2017, research and experimental expenditures are required to be capitalized beginning in 2022 and amortized over a period of 5 years for domestic expenses and 15 years for foreign expenses.

The effective tax rate for the years ended December 31, 2023 and 2022 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,	
	2023	2022
Federal statutory tax rate	21.0%	21.0%
Change in deferred tax asset valuation allowance	(24.5)%	(39.1)%
State taxes, net of federal benefit	5.3%	20.3%
Research and development tax credits	3.1%	0.6%
Stock-based compensation	(0.7)%	(0.1)%
Other	(4.2)%	(2.7)%
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,	
	2023	2022
Balance at the beginning of the year	$ 13,175	$ 11,953
Increase related to current year tax positions	1,736	2,317
Increase related to prior year tax positions	101	—
Decrease related to prior year tax positions	—	(1,095)
Balance at the end of the year	$ 15,012	$ 13,175

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, 2023 and 2022, 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 U.S. Internal Revenue Service ("IRS") examined the Company's federal corporate income tax return for the year ended December 31, 2018. The examination was completed in April 2022 and did not require any material adjustments. The federal and state income tax returns from inception to December 31, 2023 remain subject to examination.

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, 2023 and 2022. 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.

11. 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, 2023 and 2022, the Company made contributions to the 401(k) plan of $1.0 million and $1.0 million, respectively.

12. Subsequent Events

On January 16, 2024, the Company announced that due to unfavorable clinical trial results associated with the use of lirentelimab in its Phase 2 atopic dermatitis and Phase 2b chronic spontaneous urticaria trials, that the Company will halt lirentelimab-related activities across clinical, manufacturing, research and administrative functions. Accordingly, the Company's Board of Directors approved the 2024 Reorganization Plan to reduce operating costs and better align our workforce with the new clinical development plans of our business. Under the 2024 Reorganization Plan, the Company's workforce will be reduced by approximately 50% primarily during the first quarter of 2024.

The Company expects to record approximately $4 million in severance costs during the first quarter of 2024 associated with the workforce reduction.

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 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 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, 2023.

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, 2023.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm regarding our internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended, which permits us to provide only management's report in this Annual Report.

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. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

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 Rule 15d-15(d) of the Exchange Act that occurred during the fourth quarter of the year ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During our last fiscal quarter, no director or officer, as defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," each as defined in Regulation S-K Item 408.

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

Not applicable.

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, 2023.

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 Accountant 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:

(1) Financial Statements

See Index to Financial Statements included in Part II, Item 8 of this Annual Report.

(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	3.1	8/21/2023	
4.1	Specimen common stock certificate of the Registrant.	S-1/A	333-225836	4.2	7/9/2018	
4.2	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	001-38582	4.3	3/1/2022	
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	7/9/2018	
10.4+	2018 Employee Stock Purchase Plan.	S-1/A	333-225836	10.4	7/9/2018	
10.5+	Employment Letter between the Registrant and Robert Alexander, Ph.D.	S-1/A	333-225836	10.5	7/9/2018	
10.6+	Employment Letter between the Registrant and Adam Tomasi, Ph.D.	S-1/A	333-225836	10.6	7/9/2018	
10.7+	Employment Letter between the Registrant and Harlan Baird Radford, III.	10-Q	001-38582	10.1	5/10/2021	
10.8+	Executive Incentive Compensation Plan.	S-1	333-225836	10.9	6/22/2018	
10.9+	Outside Director Compensation Policy.	10-Q	001-38582	10.1	8/9/2023	
10.10+	Change in Control and Severance Policy.	S-1/A	333-225836	10.11	7/9/2018	
10.11a	Lease Agreement between the Registrant and ARE-San Francisco No. 63, LLC, dated December 4, 2019.	10-K	001-38582	10.13	2/25/2020	
10.11b	First Amendment to Lease Agreement between the Registrant and ARE-San Francisco No. 63, LLC, dated November 15, 2022.	10-Q	001-35852	10.1	5/9/2023	

10.11c	Second Amendment to Lease Agreement between the Registrant and ARE-San Francisco No. 63, LLC, dated March 27, 2023.	10-Q	001-35852	10.2	5/9/2023	
10.12#	Termination Agreement between the Registrant and Lonza AG and affiliates thereof, dated February 14, 2022.	10-K	001-38582	10.19	3/1/2022	
10.13	Master Development Services Agreement between the Registrant and Samsung Biologics Co., Ltd., dated March 31, 2022.	10-Q	001-38582	10.1	5/6/2022	
10.14	Sales Agreement between the Registrant and Cowen and Company, LLC, dated August 4, 2022.	8-K	001-38582	1.1	8/5/2022	
10.15#	Master Services Agreement, dated November 1, 2020, by and among Fujifilm Diosynth Biotechnologies UK Limited, Fujifilm Diosynth Biotechnologies Texas, LLC, Fujifilm Diosynth Biotechnologies U.S.A., Inc. and Biogen (Denmark) Manufacturing APS – a Fujifilm Diosynth Biotechnologies Group Company.	10-Q	001-38582	10.1	8/4/2022	
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (reference is made to the signature page hereto).					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
97.1	Compensation Recovery Policy.					X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X

101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)	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 14, 2024

By: /s/ Robert Alexander
Robert Alexander, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Robert Alexander and H. Baird Radford, III as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and substitution, for him or her and in his or her name, place, and stead, in any and all capacities (including his or her capacity as a director and/or officer of Allakos Inc.) to sign any or all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as they, he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agents or any of them, or their, his, or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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 14, 2024
/s/ H. Baird Radford, III **H. Baird Radford, III**	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 14, 2024
/s/ Daniel Janney **Daniel Janney**	Chair of the Board of Directors	March 14, 2024
/s/ Robert E. Andreatta **Robert E. Andreatta**	Director	March 14, 2024
/s/ Neil Graham **Neil Graham, M.D.**	Director	March 14, 2024
/s/ Steven P. James **Steven P. James**	Director	March 14, 2024
/s/ Amy L. Ladd **Amy L. Ladd, M.D.**	Director	March 14, 2024
/s/ Rand Sutherland **Rand Sutherland, M.D.**	Director	March 14, 2024
/s/ Dolca Thomas **Dolca Thomas, M.D.**	Director	March 14, 2024
/s/ Paul Walker **Paul Walker**	Director	March 14, 2024