# 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, 2018**

**OR**

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

**FOR THE TRANSITION PERIOD FROM TO**

**Commission File Number 001-38582**

# Allakos Inc.

**(Exact name of Registrant as specified in its Charter)**

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

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

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

| Title of each class | Name of each exchange on which registered |
|---|---|
| Common Stock, Par Value $0.001 Per Share | 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and therefore, cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date.

The number of shares of Registrant's Common Stock outstanding as of March 7, 2019 was 43,101,999.

Portions of the Registrant's Definitive Proxy Statement relating to the registrant's 2019 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 2018 fiscal year ended December 31, 2018.

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**PART I**

## Item 1. Business.

### Overview

We are a clinical stage biotechnology company developing AK002, our wholly owned monoclonal antibody, for the treatment of various eosinophil and mast cell related diseases. AK002 selectively targets both eosinophils and mast cells, white blood cells that are widely distributed in the body and play a central role in the inflammatory response. Inappropriately activated eosinophils and mast cells have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. As such, AK002 has the potential to treat a large number of severe diseases. AK002 has demonstrated activity in clinical trials. In these trails, AK002 depleted blood eosinophils and improved symptoms in patients with three forms of chronic urticaria ("CU") and indolent systemic mastocytosis ("ISM"), all mast cell driven diseases. The activity observed in ISM and CU suggest that AK002 could provide significant benefit to patients suffering from these diseases and highlight AK002's potential to broadly inhibit mast cells in different disease settings. We are developing AK002 for the treatment of eosinophilic gastritis ("EG"), eosinophilic gastroenteritis ("EGE"), and eosinophilic esophagitis ("EoE"). In addition, we have or are currently conducting studies in ISM, CU, and severe allergic conjunctivitis ("SAC") and are evaluating additional indications for future development.

**Figure 1. Select Eosinophil and Mast Cell Related Diseases**

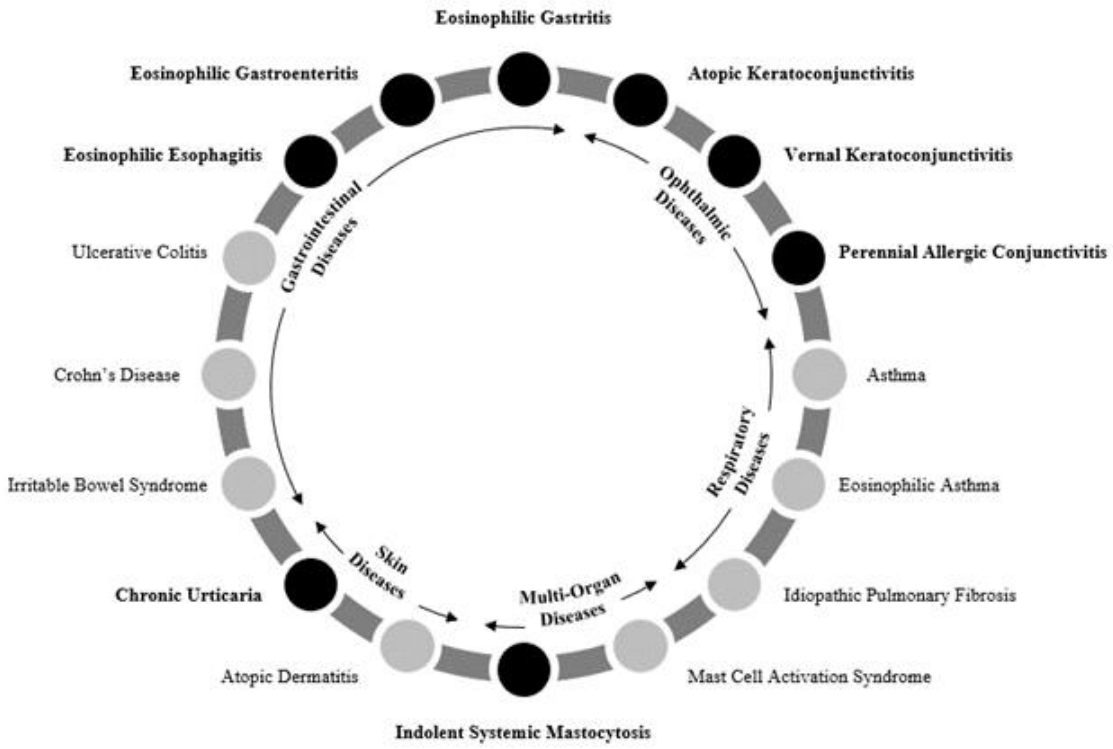



**Figure 1: We are focusing our development efforts on AK002 for the treatment of the diseases shown in bold and are evaluating additional indications for future development.**

Despite the knowledge that eosinophils and mast cells drive many pathological conditions, there are no approved therapies that selectively target both eosinophils and mast cells. AK002 binds to Siglec-8, an inhibitory receptor found on eosinophils and mast cells, which represents a novel way to selectively deplete or inhibit these important immune cells and thereby resolve inflammation. We believe AK002 is the only Siglec-8 targeting

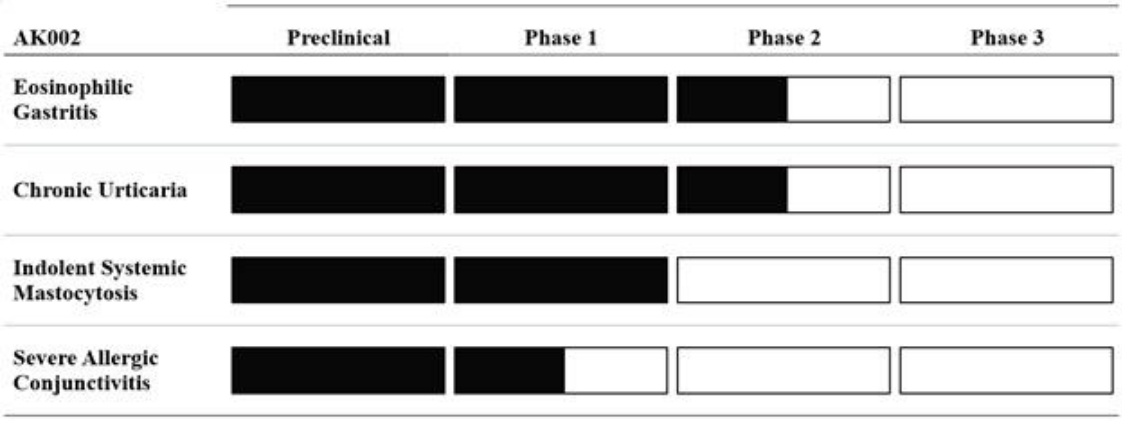
antibody currently in clinical development and has the potential to have advantages over current treatments for the diseases we are pursuing.

AK002 has demonstrated activity in 3 forms of CU and ISM, and additional studies are currently being conducted in EG/EGE and SAC. CU is a group of inflammatory skin diseases characterized by hives and severe itching resulting from the inappropriate activation of mast cells in the skin. In a phase 2 open-label six month multiple dose study of 47 antihistamine refractory patients with chronic spontaneous urticaria, cholinergic urticaria or dermatographic urticaria, patients reported high levels of disease control and many patients experienced complete resolution of symptoms while receiving AK002. Importantly, AK002 also produced high levels of response in patients that were refractory to the only approved biologic treatment option, Xolair, suggesting that AK002, if approved, could be the treatment of choice for antihistamine refractory CU patients. ISM is a disorder caused by the release of mast cell derived inflammatory mediators throughout the body resulting in severe symptoms in the skin, gastrointestinal tract, central nervous system, joints, and muscles. There are no approved treatments for ISM. In a Phase 1 open-label six month multiple dose study in 11 patients with ISM, patients reported significant improvements in symptoms and improved quality of life measures. The activity observed in ISM and CU suggest that AK002 could provide significant benefit to patients suffering from these diseases and highlight AK002's potential to broadly inhibit mast cells in different disease settings.

Previously, we have shown that AK002 depletes eosinophils. In a randomized, double-blind, placebo-controlled Phase 1 trial in 51 healthy volunteers, all doses of AK002 resulted in complete depletion of blood eosinophils within one hour after administration. The duration of depletion was dose-dependent, with a single dose of 1.0 mg/kg of AK002 suppressing eosinophils for up to 84 days. Depletion of blood eosinophils was also observed in the AK002 ISM and CU clinical studies.

We are currently testing AK002 in a double-blind, placebo-controlled Phase 2 trial in patients with EG and/or EGE. EG and EGE are severe eosinophilic inflammatory diseases of the stomach and small intestine, respectively. AK002 has received orphan drug designation for EG and EGE from the U.S. Food and Drug Administration ("FDA") and we expect to report top-line data from the Phase 2 trial in mid-2019. In addition, AK002 is being tested in a Phase 1 trial in patients with SAC. SAC is a group of allergic eye diseases that are caused by eosinophil and mast cell driven inflammation in the tissues lining the eyes and eyelids. We expect to report top-line data from the trial in SAC patients in the first or second quarter of 2019. The status of our clinical trials is shown below.

**Figure 2. AK002 Development Status**




We have prioritized our AK002 development efforts based on our assessment of the probability of clinical and regulatory success, unmet medical need and potential market opportunity. We have assembled a team with a proven track record and deep experience in antibody discovery and in clinical development, commercialization, operations and finance from companies such as Genentech, Gilead, Intermune, Novo Nordisk, Pfizer, ZS Pharma and others.

**Understanding the Foundation of Our Approach**

***Background on Eosinophils, Mast Cells and Siglec-8***

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

Eosinophils are normally present in the blood and tissues, especially in the mucosal linings of the respiratory and gastrointestinal tract. However, they can be recruited to any site of the body in the setting of inflammation. Mast cells reside within the connective tissue of a variety of 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, eosinophils and 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.

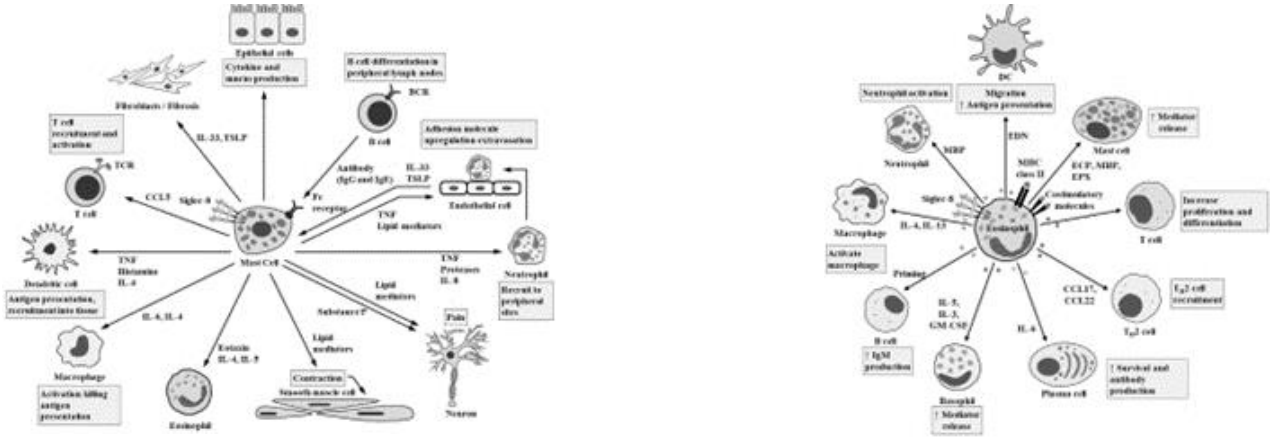
Siglec-8 is an inhibitory receptor located selectively on eosinophils, mast cells and, to a lesser extent, on basophils. Because Siglec-8 is expressed in high abundance only on eosinophils and mast cells, it presents a novel way to selectively target these important immune cells. As an inhibitory receptor, the natural function of Siglec-8 is to counteract activating signals within eosinophils and mast cells that lead to an inflammatory response. By binding to Siglec-8, AK002 is able to selectively target eosinophils and mast cells to resolve inflammation.

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

Eosinophils and mast cells respond to a variety of activating signals including those from cell-cell contact, allergens bound to IgE, cytokines (including IL-33, thymic stromal lymphopoietin ("TSLP"), IL-5, IL-4 and IL-13) and viruses (through Toll-Like Receptor-3). In response to these and other activating signals, eosinophils and 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 and toxins secreted from eosinophils and mast cells are the key cause of tissue damage and contribute to tissue fibrosis.* Eosinophil and mast cell secretions are toxic to surrounding cells and break down tissues, resulting in fibrosis and tissue remodeling.
- *Eosinophils and mast cells drive inflammation by signaling to other cells of the immune system.* Eosinophils and 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 ("GM-CSF")) 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 eosinophils and mast cells.

**Figure 3. Eosinophil and Mast Cell Functions**

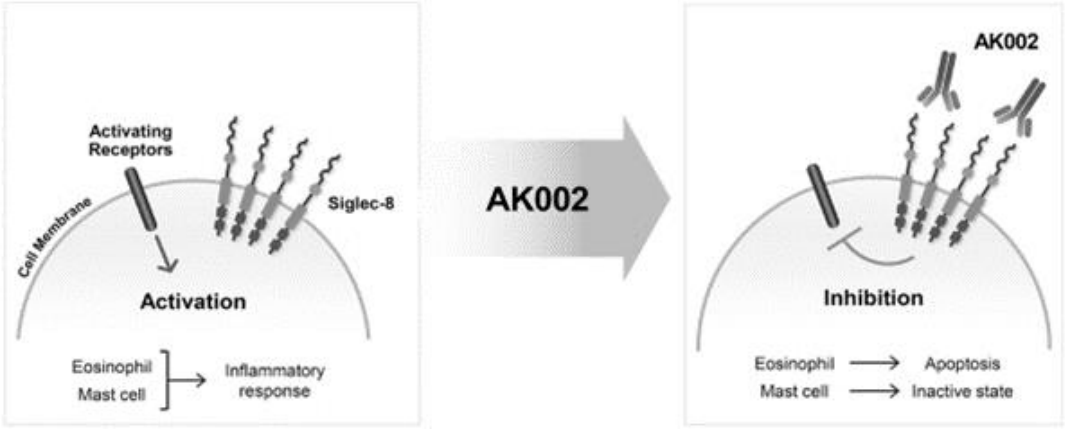


Due to their ability to respond to signals from multiple cell types and elicit responses from others, eosinophils and mast cells mediate the immediate hypersensitivity and late phase responses responsible for allergies and many innate and adaptive immune responses.

***Siglec-8 is an Attractive Target for Eosinophils and Mast Cells***

Siglec-8 (sialic acid immunoglobulin-like lectin 8) is a constitutively expressed inhibitory receptor that is restricted to eosinophils, mast cells and to a lesser extent basophils (approximately 1/100 the level on mast cells and eosinophils). The physiological function of Siglec-8 is to provide an inhibitory signal to eosinophils and mast cells. Siglec-8 exerts these effects through an intracellular immunoreceptor, tyrosine-based inhibitory motif ("ITIM") and ITIM-like motif. In contrast to approaches which block a single activating cytokine or receptor, targeting the ITIM signaling cascade (via Siglec-8) has the potential to counteract a broad array of activating signals, which could allow for the treatment of multiple diseases. Antibodies to Siglec-8 have been shown to trigger apoptosis of blood and tissue eosinophils and to inhibit the release of inflammatory mediators from mast cells. In the human clinical studies, AK002 has depeleted eosinophils and demonstrated mast cell inhibitory activity in 4 disease settings: chronic spontaneous urticaria, cholinergic urticaria, symptomatic dermographism, and ISM. This expression pattern and broad inhibitory function make Siglec-8 an attractive target for the selective depletion of eosinophils and inhibition of mast cells.

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



**Our Strategy**

AK002 has shown pharmacodynamic activity in humans and activity in a broad array of animal disease models of eosinophilic and mast cell driven diseases. We have prioritized our development efforts based on our assessment of the probability of clinical and regulatory success, unmet medical need and potential market opportunity. We have chosen to focus our wholly-owned AK002 program initially on four indications: EG, ISM, CU and SAC. The key elements of our strategy are to:

- ***Rapidly advance AK002 through clinical development in EG and EGE.*** AK002 has secured orphan drug designation for the treatment of EG and EGE with the FDA. We have completed a Phase 1 trial in healthy volunteers. In this trial, AK002 exhibited clear signs of pharmacodynamic activity by depleting blood eosinophils as soon as one hour after dosing. We are conducting a Phase 2 trial in patients with EG and/or EGE. We believe this trial, if positive, in conjunction with a future Phase 3 trial will serve as the basis for demonstrating safety and efficacy in our biologics license application ("BLA") and market authorization application ("MAA") submissions.
- ***Develop AK002 for other EGIDs.*** EG and EGE are part of a group of related diseases called eosinophilic gastrointestinal diseases ("EGIDs"). These include EoE and eosinophilic colitis ("EC"). EGIDs share the common pathology of tissue inflammation caused by the presence of elevated numbers of eosinophils. If AK002 shows activity in EG and EGE, we expect to conduct clinical trials of AK002 in EoE.
- ***Evaluate additional eosinophilic and mast cell driven conditions.*** We have completed trials for ISM and CU and are conducting an SAC study that is expected to be completed in the first or second quarter of 2019. We will evaluate further development in these and other indications.
- ***Build commercial capability and retain rights in key markets.*** If AK002 receives regulatory approval, we intend to retain the rights to it in key markets, and plan to commercialize AK002 in both the United States and Europe through a specialty sales force.

EG and other EGIDs, ISM, CU and SAC are severe diseases which lack effective treatments. We believe a significant market opportunity for AK002 exists in each of these diseases.

- ***Coordinate clinical and manufacturing process development.*** AK002 has been produced under current good manufacturing practices ("cGMP") at commercial scale utilizing the commercial process at Lonza Sales AG ("Lonza"), a Contract Development Manufacturing Organization ("CDMO"). We have signed an agreement with Lonza for BLA activities.

**AK002 Clinical Development Plan**

AK002 was designed to take advantage of the selective expression pattern and inhibitory function of Siglec-8, an inhibitory receptor found on eosinophils, mast cells, and to a lesser extent, on basophils. AK002 is a humanized antibody that binds to Siglec-8 with high affinity (bivalent binding avidity (K D ) = 17 pM, determined by surface plasmon resonance analysis). The high expression level of Siglec-8 on eosinophils and mast cells allows AK002 to selectively deplete eosinophils and inhibit mast cells. AK002 is a non-fucosylated IgG1 antibody engineered to have potent antibody-dependent cellular cytotoxicity ("ADCC"). ADCC is a mechanism whereby the binding of an antibody like AK002 triggers an effector cell of the immune system (usually a natural killer ("NK") cell) to destroy the antibody-bound cell. This provides AK002 with an additional mechanism to deplete eosinophils present in blood, where NK cells also reside. As a result of these dual modes of action, AK002 has been shown to deplete eosinophils in blood and tissue, and to inhibit the release of inflammatory mediators from mast cells.

AK002 has demonstrated activity in a broad array of animal disease models of eosinophilic and mast cell-driven diseases. Consistent with these experiments, human trials have shown that AK002 depletes blood eosinophils and inhibits mast cell symptoms in 4 different diseases (ISM, chronic spontaneous urticaria, cholinergic urticaria, and symptomatic dermographism). AK002 has generally been well tolerated in our clinical studies. The most common adverse event has been the occurrence of mild to moderate infusion-related reactions ("IRRs") (flushing, feeling of warmth, headache, nausea or dizziness), which occurred mostly during the first infusion and diminished or did not occur on subsequent infusions.

***Eosinophilic Gastritis and Eosinophilic Gastrointestinal Disorders***

*Disease Overview*

EGIDs are chronic inflammatory disorders that share a similar eosinophilic driven inflammation that occurs along different segments of the gastrointestinal ("GI") tract. Based on the site of eosinophilic infiltration the EGIDs are subcategorized into EoE (esophagus), EG (stomach), EGE (duodenum and small intestine) and EC (colon). The EGIDs affect collectively up to 300,000 patients in the United States, though individually they are orphan diseases.

EG is a rare disease that is characterized by chronic inflammation due to patchy or diffuse infiltration of eosinophils into layers of the stomach. Symptoms commonly include abdominal pain, nausea, vomiting, diarrhea, malnutrition and weight loss. EG can occur with eosinophilia isolated to the stomach, or often in combination with eosinophilia of the small intestine. Diagnosis is established based on clinical presentation (gastrointestinal symptoms) combined with increased tissue eosinophils in biopsy specimens from the stomach and/or duodenum without any other cause for the eosinophilia. The presence of greater than 30 eosinophils per high powered field ("hpf") in 5 stomach biopsies identifies the presence of EG and the presence of greater than 30 eosinophils per hpf in 3 duodenal biopsies identifies the presence of EGE. The estimated prevalence of EG in the United States is approximately 20,000 to 25,000 patients, and the estimated prevalence of EGE in the United States is approximately 25,000 patients and we believe these diseases may be significantly underdiagnosed based on our conversations with gastroenterologists.

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

*Current Therapies and Limitations*

There are no FDA-approved treatments for EG or EGE. Current therapies and disease management strategies include restricted/elemental diets and systemic or topical corticosteroids. Restricted/elemental diets are designed to avoid foods which trigger symptoms. Unfortunately for most patients the restricted/elemental diets are only partially effective and mainly used as a strategy to provide nutrition despite continuing symptoms. Corticosteroids, systemic or topical, can provide symptom relief, but are not appropriate for long-term treatment due to their numerous side effects. By reducing the number of blood and tissue eosinophils and inhibiting mast cells, AK002 may be effective in the treatment of patients with EG or EGE.

*Clinical Results (healthy volunteer study)*

AK002 was tested in a randomized, double-blind, placebo-controlled, dose-escalating Phase 1 trial conducted in Melbourne, Australia. 51 healthy volunteers were randomized to receive doses of AK002 (0.001, 0.003, 0.01, 0.03, 0.1, 0.3, or 1.0 mg/kg) or placebo. The primary endpoints of the trial were safety and tolerability. The secondary endpoints included pharmacokinetic and pharmacodynamic ("PK/PD") measurements, including changes in the absolute peripheral blood counts of eosinophils.

As shown in Figure 5, with respect to the secondary endpoints, all doses of AK002 tested resulted in complete depletion of blood eosinophils one hour after administration, clearly demonstrating the pharmacodynamic activity of AK002. The duration of depletion was dose-dependent with a single dose of 1.0 mg/kg of AK002 suppressing eosinophils for up to 84 days. AK002's pharmacokinetic half-life was determined to be 18 days.

**Figure 5. Single Dose Placebo and AK002 Eosinophil Response**

| | | Blood Eosinophils $10^3$/mL | | | |
|---|---|---|---|---|---|
| **Dose Cohort (mg/kg)** | **Placebo Pre-dose** | **Placebo 1 Hr Post-dose** | **AK002 Pre-dose** | **AK002 1 Hr Post-dose** | **Minimal Duration Eos Depletion** |
| 0.001 | NA | NA | 70 | 0 | 1 Day |
| 0.003 | 120 | 70 | 160 | 0 | 2 Days |
| 0.01 | 210 | 150 | 160 | 0 | 4-7 Days |
| 0.03 | 150 | 150 | 160 | 0 | 7-14 Days |
| 0.1 | 100 | 80 | 250 | 0 | 14-28 Days |
| 0.3 | 180 | 140 | 180 | 0 | 28 Days |
| 1.0 | 60 | 40 | 120 | 0 | 56-84 Days |

In the multi-dose portion of the trial, subjects received monthly doses of 0.3 mg/kg. Monthly administrations of this dose provided sustained eosinophil depletion for the duration of dosing.

*Safety (All Studies)*

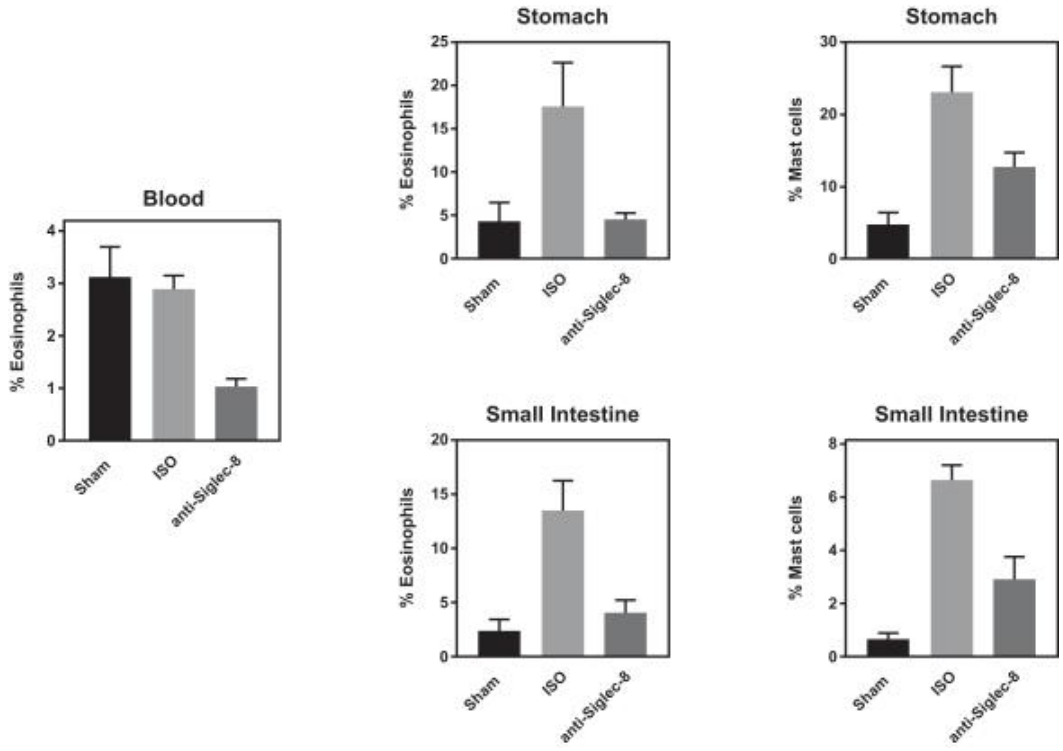
AK002 has generally been well tolerated in our clinical trials. The most common adverse event has been the occurrence of mild to moderate IRRs (consisting of flushing, feeling of warmth, headache, nausea or dizziness) which occurred in 22% of first infusions and 3% of subsequent infusions. Temporal interruption of the AK002 infusion and minimal intervention generally resulted in prompt resolution of symptoms and ability to resume the infusion without further complications, although there have been instances when an IRR has resulted in a subject being discontinued from a trial.

There have been no clinically significant effects of AK002 identified in vital signs, ECGs, clinical laboratory parameters (including hematology, clinical chemistry and urinalysis) or physical examinations. Transient (resolving within 24 hours) decreases in lymphocyte count have been observed after AK002 infusion, as seen with certain other monoclonal antibodies, that were not associated with any adverse event.

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

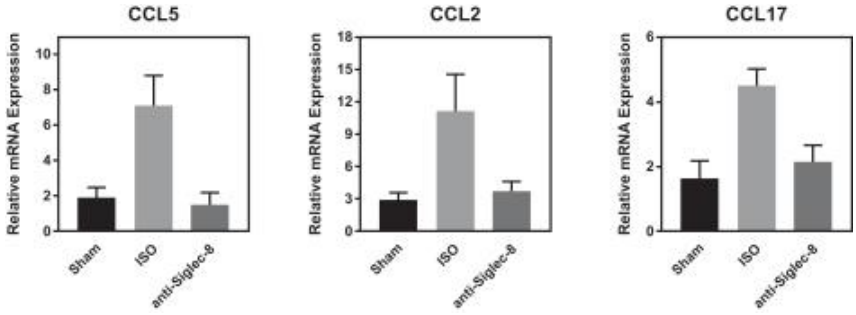
In this model, two groups of Siglec-8 transgenic mice were sensitized with ovalbumin to induce eosinophil and mast cell driven gastrointestinal inflammation similar to that observed in EG and other EGIDs. A third group of animals was administered phosphate buffered saline to serve as normal unsensitized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

**Figure 6. EG/EGE Model Eosinophil and Mast Cell Counts in Blood, Stomach and Small Intestine**




Anti-Siglec-8 treatment also reduced the levels of multiple important chemokines (CCL5/Rantes, CCL2/MCP-1, CCL17) to the levels of sham control animals. Chemokines are known to recruit and activate cells of the innate and adaptive immune system. By normalizing chemokine secretions, AK002 may be able to reduce further recruitment of immune cells and thereby interrupt the inflammatory cascade.

**Figure 7. Chemokine Levels in the EG/EGE Mouse Model**



*Phase 2 Trial*

AK002 has received orphan drug designation in the United States for the treatment of EG and EGE. We have initiated a randomized, double-blind, placebo-controlled Phase 2 trial with AK002 in approximately 60 patients with active, moderate to severe, biopsy-confirmed EG (stomach >30 eosinophils/hpf in 5 hpf) and/or EGE (duodenum >30 eosinophils/hpf in 3 hpf). Patients were randomized 1:1:1 to receive: (a) 0.3 mg/kg for the first month followed by three doses of 1.0 mg/kg AK002 given monthly, (b) 0.3 mg/kg for the first month followed by 1.0 mg/kg, 3.0 mg/kg and 3.0 mg/kg given monthly, or (c) monthly placebo. The primary endpoint is the reduction in gastric or duodenal eosinophils post-treatment with AK002. The secondary endpoints include changes in EG and EGE patient symptoms, such as abdominal pain, nausea, vomiting and diarrhea, as reported by patients using our proprietary daily Patient Reported Outcome ("PRO") questionnaire. The PRO was developed based on published guidance from the FDA on the development of PRO instruments, and is expected to be used to help determine safety and efficacy in future clinical trials.

A number of EG patients enrolled in the trial also have concomitant EoE. Consequently, it may be possible to evaluate response to treatment with AK002 in EoE as well. Patients completing the randomized portion of the trial will be eligible to enroll in a nine month safety exposure trial. Top-line data from the Phase 2 trial are expected during mid-2019. Based on discussions with the FDA, we believe that this Phase 2 trial, if successful, and a single Phase 3 trial, if successful, may be sufficient for regulatory approval of AK002 in EG and EGE.

**Figure 8. EG Phase 2 Trial Design**

| Design | | Key Endpoints |
|---|---|---|
| **•Randomized, double-blind, placebo controlled**<br>**•60 Patients – 3 arms**<br>**—20 patients 0.3 mg/kg, then 1.0 mg/kg**<br>**—20 patients 0.3 mg/kg, then 1.0 mg/kg, then 3.0 mg/kg and 3.0 mg/kg**<br>**—20 patients placebo**<br>**•Multiple doses (x4)** | **Primary** | •Eosinophils per high powered field from gastric or duodenal biopsies |
| | **Secondary** | •Patient reported outcomes: abdominal pain, nausea, diarrhea, vomiting<br>•Assessment of comorbid EOE |

***Indolent Systemic Mastocytosis***

*Disease Overview*

ISM is a rare disease characterized by the clonal proliferation and accumulation of mast cells in the bone marrow, respiratory and gastrointestinal tracts, and organs such as the skin, liver, spleen and brain. Common symptoms include pruritus, flushing, headache, cognitive impairment, fatigue, diarrhea, gastrointestinal cramps, hypotension and skin lesions, as well as an increased risk for osteoporosis and anaphylaxis, which in some cases can be life threatening. The symptoms of ISM are attributed to mast cell activation and the systemic release of mediators. Approximately 30,000 patients in the United States suffer from ISM. AK002 has received orphan drug designation from the European Medicines Agency for the potential treatment of ISM.

*Current Therapies and Limitations*

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

*Clinical Results*

AK002 has been evaluated in an open-label, single and multiple ascending dose Phase 1 trial in patients with ISM. The single dose portion of this trial was completed during the second quarter of 2017, and the six month multi-dose portion completed in the first quarter of 2019. The primary endpoints of this trial were safety and tolerability. Key secondary endpoints were the PK/PD profile, peripheral counts of eosinophils and patient-reported mastocytosis disease symptoms including itching, hives, skin flushing, diarrhea, abdominal pain, fatigue, headache, difficulty concentrating and muscle and joint pain. In the single dose portion, 13 patients received single escalating doses of 0.0003 to 1.0 mg/kg, including three patients receiving 0.3 mg/kg and three patients receiving 1.0 mg/kg of AK002. Five out of six patients receiving 0.3 or 1.0 mg/kg reported to the study investigators that they had improvements in symptoms, including diarrhea, abdominal pain, fatigue, pruritus, difficulty concentrating and headaches.

In the multi-dose portion of the trial, six patients received six doses of 1.0 mg/kg of AK002 given monthly and five patients received 1.0 mg/kg for the first month and then monthly doses of 3.0 to 10 mg/kg of AK002 for five months. Eosinophil depletion was observed for all patients throughout the dosing period with AK002. ISM symptoms and quality of life were assessed using an Allakos created PRO, the Mastocytosis Questionnaire ("MSQ"), and two published questionnaires, the Mastocytosis Activity and Symptom Severity questionnaire ("MAS") and the Mastocytosis Quality of Life questionnaire ("MC-QoL"). The MSQ is a proprietary daily PRO Mastocytosis Questionnaire that we developed based on published guidance from the FDA on the development of PRO instruments, and is expected to be used to help determine safety and efficacy in future clinical trials. The questionnaire consists of nine symptom assessments, with each symptom being scored on a 0-10 scale and higher values representing greater symptom burden (total score 0-90 points). For each PRO, baseline scores were collected over 14 to 28 days and compared to scores at Weeks 21 to 22, two weeks after the final AK002 dose. PRO data for the patients in the multidose portion of the trial are presented in Figure 5. Consistent with the improvements reported in the single ascending dose study, AK002 produced clinically significant improvement in patient symptoms in multiple symptoms across all three PROs used in the study.

**Figure 9. Patient Reported Outcomes from multi-dose portion of ISM trial**

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

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

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

| MC-QoL Domain (N=11) | Median Change from Baseline at Weeks 21 to 22 |
|---|---|
| Symptoms | -39% |
| Social Life / Functioning | -42% |
| Emotions | -57% |
| Skin | -44% |

AK002 has generally been well tolerated in the Phase 1 ISM study. The most common adverse event was the occurrence of mild to moderate infusion-related reactions (flushing, feeling of warmth, headache, nausea or dizziness), which occurred mostly during the first infusion.

***Chronic Urticarias – Cholinergic Urticaria, Chronic Spontaneous Urticaria, Symptomatic Dermatographism***

*Disease Overview*

CU is a group of mast cell driven skin conditions which are characterized by recurrent transient pruritic wheal and flare type skin reactions and, in roughly 40% of patients, angioedema. Symptoms include hives, itching, redness, raised welts, burning, warmth, tingling and irritation of the skin. Patients with CU are often severely impaired in their quality of life, with negative effects on sleep, daily activities, school/work life and social interactions. Urticaria symptoms are caused by degranulation of dermal mast cells, with IgE signaling believed to contribute to mast cell activation in many cases. The most common forms of CU are chronic spontaneous urticaria (“CSU”), cholinergic urticaria and symptomatic dermatographism.

Despite sharing similar inflammatory pathology, urticarias differ in the triggers that cause the inflammatory response. Cholinergic urticaria patients 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 hiving and itching following a minor stroking pressure, rubbing or scratching of the skin. In CSU, itchy, wheal-and-flare-type skin reactions spontaneously appear on the skin at any time of the day or night. In most CSU patients, an underlying cause of CSU cannot be identified making a causal and/or curative treatment difficult. We conservatively estimate that approximately 200,000-500,000 patients with severe CSU, cholinergic urticaria and symptomatic dermatographism could be candidates for therapy with AK002 in the U.S.

*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 that 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 that do not respond to or are unable to tolerate high dose antihistamines have few options. For cholinergic urticaria and symptomatic dermatographism patients, it is recommended that they avoid target triggers such as overheated spaces, hot baths/showers, exercise, specific food allergens and excessive

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

*Clinical Results*

We conducted an open-label Phase 2 trial with AK002 in patients with uncontrolled chronic urticaria despite treatment with H1 antihistamines at up to 4x the labeled dose. The study enrolled four cohorts consisting of 13 xolair naïve patients with chronic spontaneous urticaria patients, 11 Xolair refractory patients with chronic spontaneous urticaria (average duration of Xolair treatment 10 months at doses as high as 600mg/month), 11 patients with cholinergic urticaria, and 10 patients with symptomatic dermographism. Baseline symptom scores, as measured by Urticaria Control Test ("UCT") and Urticaria Activity Score ("UAS7") were collected over a 4-week screening period. Patients with baseline UCT scores of less than 12, indicative of poorly controlled urticaria, were enrolled in the study and treated with up to 6 doses of AK002 given once monthly. Patients received an initial dose of 0.3 mg/kg at baseline, followed by a dose of 1.0 mg/kg on day 28, and then received monthly doses of either 1.0 or 3.0 mg/kg for a total of 6 doses. The primary endpoint of the trial was patient-reported symptoms measured by the UCT. Secondary endpoints include safety and tolerability, as well as patient-reported symptoms as measured by UAS7 (CSU patients only), pulse controlled ergometry (cholinergic urticaria patients only), and FRIC testing (symptomatic dermographism patients only).

Results for each cohort are shown in Figure 10. Patients in all cohorts reported high levels of disease control and many patients experienced complete resolution of symptoms while receiving AK002. Importantly, AK002 also produced high levels of response in patients that were refractory to Xolair, the only approved biologic treatment option, suggesting that AK002 could the treatment of choice for antihistamine refractory CU patients. Additionally, AK002 depleted blood eosinophils in subjects throughout the dosing period.

**Figure 10. Data from the Phase 2 CU clinical trial**

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

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

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

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

AK002 has generally been well tolerated in the Phase 2 CU study. The most common adverse event was the occurrence of mild to moderate IRRs (flushing, feeling of warmth, headache, nausea or dizziness), which occurred in 34% of first in fusions and 4% of subsequent infusions.

***Severe Allergic Conjunctivitis***

*Disease Overview*

Atopic keratoconjunctivitis ("AKC"), vernal keratoconjunctivitis ("VKC") and perennial allergic conjunctivitis ("PAC") are a set of allergic ocular conjunctival diseases primarily associated with an IgE-mediated hypersensitivity reaction. We are focused on the severe forms of these diseases, which are collectively referred to as severe allergic conjunctivitis ("SAC"). These conditions are often caused by airborne allergens, such as grass and tree pollens, coming into contact with the eyes, which induces IgE mediated mast cell degranulation and allergic inflammation. The inflammatory mediators released by the mast cell result in inflammation and the infiltration of eosinophils, neutrophils and other immune cells. Eosinophils and mast cells are believed to be the main effector cells, with protease secretions directly damaging the conjunctiva, and play a key role in triggering and maintaining the inflammatory response. Symptoms include itching, hyperemia, light sensitivity (photophobia), pain, eye discharge and the sensation of having a foreign body in the eye. These symptoms can affect quality of life and daily activities, such as reading, driving and being in bright outdoor environments. In addition, patients with untreated disease, in particular those with VKC and AKC, can experience remodeling of the ocular surface tissues that can lead to vision loss. In addition to the primary symptoms of allergic conjunctivitis, a high correlation of allergic rhinitis, allergic asthma and atopic dermatitis comorbidities occur in this patient population. We believe that approximately 50,000-150,000 patients in the United States suffer from severe AKC, VKC or PAC and could be candidates for treatment with AK002.

*Current Therapies and Limitations*

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

*Phase 1 Trial*

We are conducting an open-label Phase 1 trial with AK002 in patients with SAC. The trial is enrolling patients with three different forms of allergic conjunctivitis: AKC, VKC and PAC. Thirty patients enrolled (13 AKC, 16 PAC and 1 VKC) and will receive six monthly doses of AK002. The primary endpoint of the trial will be safety and tolerability. Key secondary endpoints include patient-reported symptom measures of ocular itch, pain, lacrimation, photophobia and foreign body sensation. In addition, a number of patients enrolled in the trial will also have

concomitant allergic rhinitis, asthma, and atopic dermatitis. Consequently, it may be possible to evaluate response to treatment with AK002 in these allergic conditions as well. Given that the trial is an open-label study, it is not designed to show statistical significance. We expect to report data from this trial in the first or second quarter of 2019.

**Figure 11. SAC Phase 1 Trial Design**

| Design | | Key Endpoints |
|---|---|---|
| **•Open-label trial**<br>**•30 patients – 3 cohorts**<br>**—Atopic keratoconjunctivitis**<br>**—Vernal keratoconjunctivitis**<br>**—Perennial allergic conjunctivitis**<br>**•Multiple doses (x6)**<br>**•0.3 mg/kg, then 1.0 mg/kg, then 1.0 or 3.0 mg/kg** | **Primary** | •Safety and tolerability |
| | **Secondary** | •Patient reported outcomes: ocular itch, pain, lacrimation, photophobia, foreign body sensation<br>•Assessment of comorbid atopic dermatitis, asthma and/or rhinitis |

**Preclinical Results**

***AK002 Results in Animal Disease Models Suggest Broad Activity***

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

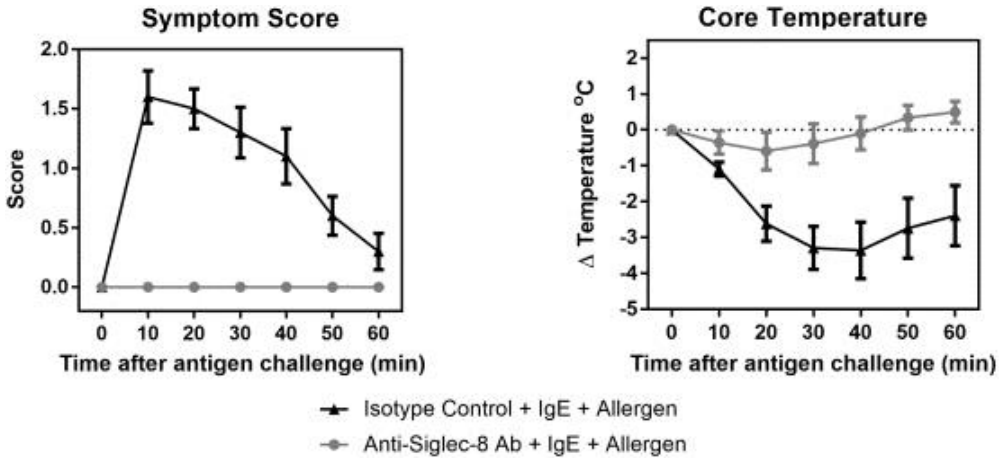
AK002 has completed short- and long-term toxicity studies in Siglec-8 transgenic mice. Chronic weekly dosing for six months with AK002 in transgenic mice at dose levels of 50 or 100 mg/kg resulted in no adverse AK002-related findings in mortality, clinical observations, body weight, food consumption and anatomic pathology after the end of dosing. Non-adverse findings included decreases in eosinophil counts in both sexes at 50 mg/kg/week, which persisted through the recovery period. These findings reflect the expected pharmacology of AK002. The no-observed-adverse-effect-level of AK002 after chronic dosing for six months was 100 mg/kg/week.

We have shown that AK002 or antibodies to Siglec-8 have broad activity in animal disease models (eosinophilic gastroenteritis, anaphylaxis, fibrosis and chronic obstructive pulmonary disease) and in human *ex vivo* diseased tissue (eosinophilic gastrointestinal disease, mastocytosis, atomic dermatitis and lung). In these models, anti-Siglec-8 antibodies have significantly reduced eosinophil and inhibited mast cells. The activity in these models suggests AK002 has the potential to treat eosinophil and mast cell inflammation in a number of disease settings and highlights AK002's ability to inhibit the inflammatory cascade triggered by different activating signals.

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

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

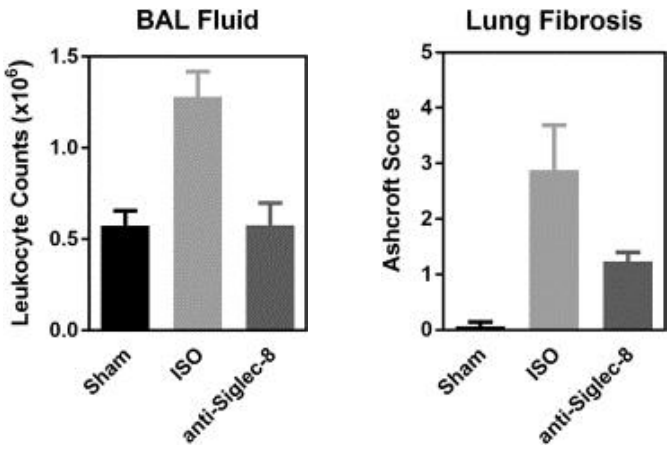
**Figure 12. Effects of Anti-Siglec-8 in a Mouse Model of Systemic Anaphylaxis**




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

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

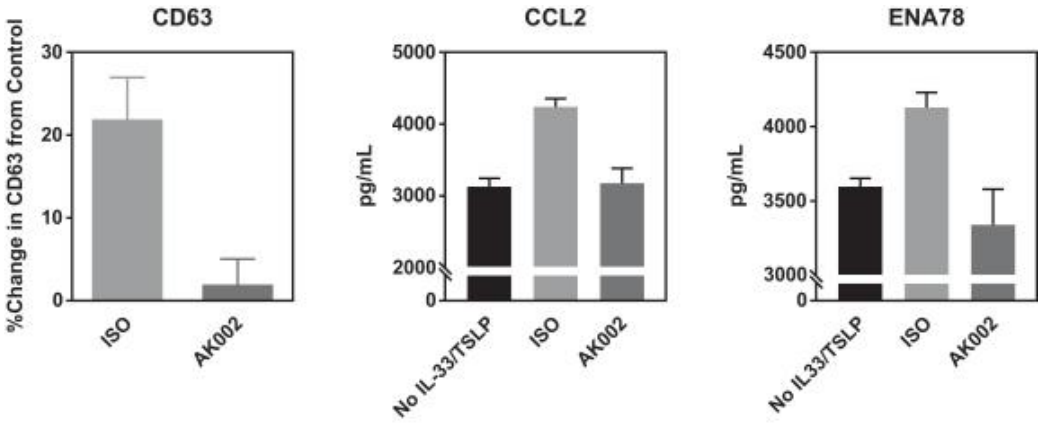
**Figure 13. Leukocyte Counts and Lung Fibrosis in Bleomycin Lung Fibrosis Model**




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

IL-33 combined with TSLP is a potent activator of mast cells and results in increased expression of the mast cell activation marker CD63. Mast cells isolated from skin showed a 20% increase in the expression of CD63 after overnight exposure to IL-33 and TSLP. In contrast, skin mast cells treated with AK002 along with IL-33 and TSLP did not show increased activation, with CD63 levels remaining similar to control levels (no IL-33 and TSLP exposure). In addition, the levels of chemokines CCL2 and ENA78 did not increase after stimulation with IL-33 and TSLP in the presence of AK002. Chemokines are known to recruit and activate cells of the innate and adaptive immune system. By normalizing chemokine secretions, AK002 may be able to prevent further recruitment of immune cells and thereby interrupt the inflammatory cascade.

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




**AK001**

We initially began developing two product candidates, AK001 and AK002, both of which are monoclonal antibodies targeting Siglec-8. These compounds entered clinical development in 2015 and 2016, respectively. Due to the greater activity of AK002, we decided to focus our development efforts on AK002 and discontinued the

development of AK001 in 2017. We have no current plans to continue development of AK001, but may choose to do so in the future.

**Preclinical Programs**

We are developing two additional antibodies targeting novel immune system receptors for the treatment of cancer. These antibodies are being assessed in a variety of animal models.

**Competition**

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

We are not aware of any other company or organization that is conducting clinical trials of a product candidate that targets both eosinophils and mast cells, including any product candidate that specifically targets Siglec-8. The competition we may face with respect to each of the indications we are targeting with AK002 includes:

- ***EG, EGE and EoE.*** Currently, there are no therapies that have been approved by the FDA specifically for EG, EGE or EoE. Several companies, including but not limited to, Regeneron, AstraZeneca, Celgene, Shire, and Dr. Falk Pharma have or are conducting studies in these indications.
- ***ISM.*** We are not aware of any FDA-approved treatment options that target the underlying causes of ISM. Blueprint Medicines initiated a phase 2 trial evaluating avapritinib in smoldering systemic mastocytosis and ISM in the second half of 2018.
- ***CU.*** Xolair is a FDA-approved drug approved for the treatment of CSU. We are not aware of any FDA-approved treatment options for cholinergic urticaria or symptomatic dermatographism. Companies conducting studies in chronic spontaneous urticaria include: Novartis Pharmaceuticals (ligelizumab), Genentech (fenebrutinib), and Gossamer Bio (GB100).
- ***SAC.*** The products that are currently available for treatment of SAC only provide temporary relief for most patients and have little effect on moderate to severe cases. We are not aware of any other company specifically targeting SAC.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

**Sales and Marketing**

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

**Manufacturing**

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

We do not currently have the infrastructure or internal capability to manufacture our product candidates for use in clinical development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates in compliance with cGMP requirements clinical trials under the guidance of members of our organization. In the case of AK002, we rely on a single third-party manufacturer, Lonza, and we currently have no alternative manufacturer in place. We do not have long-term supply agreements and we purchase our required drug product on a purchase order basis. We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We have personnel with significant technical, manufacturing, analytical, quality, regulatory, including cGMP, and project management experience to oversee our third-party manufacturers and to manage manufacturing and quality data and information for regulatory compliance purposes.

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

**In-Licensing Agreements**

We have entered into two in-licensing agreements with third-parties for the development, manufacturing and commercialization of our products including AK002. The specific terms of the individual agreements are discussed in further detail below. In aggregate, we anticipate our total royalty obligation on AK002 from these two agreements will be a mid single digit percentage of net sales by us and our affiliates and sublicensees.

***Exclusive License Agreement with The Johns Hopkins University***

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

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

Our royalty obligation with respect to each licensed product in a country extends until the later of the expiration of the last-to-expire patent licensed from JHU covering the licensed product in the country or the

expiration of a specified number of years after the first commercial sale of any licensed product in any country. The latest possible expiration date of patents licensed under the agreement is 2021 in all applicable countries, in the absence of any patent extensions that may be available for such patents.

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

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

Under the license agreement, we are obligated to pay BioWa an annual commercial license fee of $40,000 until such time as BioWa receives royalty payments. We may also become obligated to make payments to BioWa aggregating up to $41.0 million based on achieving specified milestones, and to pay low single-digit royalties to BioWa based on net sales of licensed product by us and our affiliates and sublicensees. Our royalty obligation to BioWa with respect to each licensed product in a country extends until the later of the expiration of the last-to-expire licensed patent covering the licensed product in the country or the expiration of either regulatory exclusivity or a specified number of years after the first commercial sale of the licensed product in the country, whichever is later.

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

**Government Regulation**

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

***U.S. Drug Development***

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

disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

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

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

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

***Preclinical Studies and IND***

The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of

reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

***Clinical Trials***

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

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

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

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

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

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious

and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug or biologic, findings from animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that our product candidates do not undergo unacceptable deterioration over their shelf life.

***NDA/BLA Review Process***

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

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA or BLA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through September 30, 2016, the user fee for an application requiring clinical data, such as an NDA or BLA, is $2.3 million. PDUFA also imposes an annual product fee for human drugs and biologics (approximately $97,750) and an annual establishment fee (approximately $580,000) on facilities used to manufacture prescription drugs and biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

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

Before approving an NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not

approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

***Orphan Drugs***

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

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

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

***Expedited Development and Review Programs***

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for fast track designation if they are intended to treat a serious or life threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast

track status any time before receiving NDA or BLA approval, but ideally no later than the pre-NDA or pre-BLA meeting.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

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

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

***Abbreviated Licensure Pathway of Biological Products as Biosimilar or Interchangeable***

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

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

In addition, an application must include information demonstrating that:

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

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

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

FDA approval is required before a biosimilar may be marketed in the United States. However, complexities associated with the large and intricate structures of biological products and the process by which such products are manufactured pose significant hurdles to the FDA's implementation of the law that are still being worked out by the FDA. For example, the FDA has discretion over the kind and amount of scientific evidence—laboratory, preclinical and/or clinical—required to demonstrate biosimilarity to a licensed biological product.

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

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

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

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

***Post-Approval Requirements***

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, requirements to report adverse experiences and comply with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

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

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

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

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

***Other U.S. Regulatory Matters***

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

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

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

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

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

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

***U.S. Patent-Term Restoration and Marketing Exclusivity***

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

restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

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

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

***European Union Drug Development***

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

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

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

***European Union Drug Review and Approval***

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

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP"), of the European Medicines Agency ("EMA"), and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State ("RMS"). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics ("SPC"), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

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

***Coverage and Reimbursement***

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

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

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for

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

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

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

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

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our

products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

**Employees**

As of December 31, 2018, we had 62 full-time employees, 40 of whom were engaged in research and development activities. None of our employees are represented by a labor union or covered under a collective bargaining agreement.

**Facilities**

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

From time to time, we may become involved in litigation or other legal proceedings. 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, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

**Intellectual Property**

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

We believe that we have substantial know-how and trade secrets relating to our technology and product candidates. Our patent portfolio as of March 7, 2019 contains seven issued and unexpired U.S. patents and eight pending U.S. patent applications that are solely owned or exclusively licensed by us and numerous foreign counterparts of these patents and patent applications.

We have exclusively licensed from JHU five issued and unexpired U.S. patents and also foreign counterparts, with claims granted in Europe and Japan. The JHU licensed patent rights include issued U.S. patents with claims that recite anti-Siglec-8 antibodies comprising the CDRs of a particular antibody and methods of use a class of antibodies that bind to Siglec-8 for treating particular diseases. We own two granted U.S. patents that claim the active component of AK002 (an anti-Siglec-8 antibody), pharmaceutical compositions comprising AK002, and methods for the treatment of particular diseases using antibodies to Siglec-8, with a projected expiration date in 2035 in the absence of patent extensions. Similar patent applications are pending in Europe and Japan. We have

eight further pending families of patent applications that include U.S. and foreign applications relating to methods of treatment for treating particular diseases using antibodies to Siglec-8 and methods of delivering antibodies to Siglec-8. We have also filed patent applications with claims pending relating to antibodies in preclinical development and methods for treating cancer with these antibodies. We also have a non-exclusive license to intellectual property from BioWa and Lonza regarding the expression and manufacturing of monoclonal antibodies in particular mammalian host cell lines.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review while the patent is in force. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended.

Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates, including AK002, 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.

**Available Information**

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

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

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

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

**Item 1A. Risk Factors.**

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

**Risks Related to Our Financial Position and Need for Additional Capital**

***We are in the early stages of clinical drug development and have a very 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 an early 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 AK002, our lead compound. All of our product candidates currently under development, other than AK002, are in preclinical development. We have not yet demonstrated our ability to successfully complete any large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale drug or arrange for a third-party to do so on our behalf or conduct sales and marketing activities. As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-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 $43.5 million, $23.6 million and $17.1 million for the years ended December 31, 2018, 2017 and 2016. As of December 31, 2018, we had an accumulated deficit of $104.1 million. We have devoted substantially all of our resources and efforts to research and development. Our lead compound, AK002, is in clinical development, and our other product candidates are in preclinical development. As a result, we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to develop and market additional potential products.

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

and expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

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

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

- successful and timely completion of preclinical and clinical development of our lead compound, AK002, and any other future product candidates;
- timely receipt of marketing approvals for AK002 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 AK002 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 AK002 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, AK002 and our other product candidates. In addition, if we obtain marketing approval for any of our product

candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. We have also incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

As of December 31, 2018, we had $178.9 million in cash, cash equivalents and marketable securities, which includes proceeds from our initial public offering ("IPO") and concurrent private placement that we completed on July 23, 2018. 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 AK002 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 AK002 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 of AK002 or any of our other product candidates. We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

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

***We are dependent on the success of our lead compound, AK002, which is currently in multiple clinical trials. If we are unable to obtain approval for and commercialize AK002 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 AK002, our lead compound, for one or more indications. AK002 is in the early stages of development and we are investing the majority of our efforts and financial resources in the research and development of AK002 for multiple indications. AK002 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 AK002, or any other product candidates, before we receive marketing approval from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of AK002 will depend on several factors, including the following:

- successful and timely completion of our ongoing clinical trials of AK002;
- initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- efficacy, safety and tolerability profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals for AK002 from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers;

- the maintenance of existing or the establishment of new scaled production arrangements with third-party manufacturers to obtain finished products that are appropriately packaged for sale;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio, including our licensed intellectual property;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

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

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

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

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

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application ("BLA") or New Drug Application ("NDA"), or other submission or to obtain regulatory approval in the United States or elsewhere;

- we may be unable to demonstrate to the FDA, EMA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy 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.

***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, because certain of our clinical trials of AK002 are focused on indications with small patient populations, 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:

- 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 demonstrate safety and efficacy to the satisfaction of regulatory authorities or otherwise produce positive results.***

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the

process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

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

- obtaining marketing 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;
- 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 we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may incur unplanned costs, be delayed in obtaining marketing approval, if at all, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements or have the drug removed from the market after obtaining marketing approval.

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

We currently have no drugs approved for sale and we cannot guarantee that we will ever have marketable drugs. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future larger registration clinical trials will be successful. This is because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. In particular, no compound with the mechanism of action of AK002 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, 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, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in planned clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our products, if approved, such as boxed warnings or contraindications in labeling, or a risk evaluation and mitigation strategy, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;

- the availability of coverage and adequate reimbursement and pricing by third-parties and government authorities;
- relative convenience and ease of administration;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to the product candidate; and
- the approval of other new therapies for the same indications.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be harmed. AK002 is currently administered as an intravenous treatment, which is less convenient for patients than some other methods of administration, such as an orally delivered drug.

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

Our projections of both the number of people who have some of the diseases we are targeting, as well as the subset of people with these diseases who have the potential to benefit from treatment with AK002 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 AK002 and any other future product candidates may be limited or may not be amenable to treatment with AK002 and any other products, if and when approved. Even if we obtain significant market share for AK002 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 AK002 into clinical development and through to regulatory approval and commercialization. Our other product candidates are at even earlier stages of development than AK002 and may fail in development or suffer delays that adversely affect their commercial viability.***

All of our 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 AK002. The success of any product candidates we may develop will depend on many factors, including the following:

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

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

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

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

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

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

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

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

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

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

We are not aware of any other company or organization that is conducting clinical trials of a product candidate that targets both eosinophils and mast cells, including any product candidate that specifically targets Siglec-8. The competition we may face with respect to the indications we are targeting with AK002 includes, without limitation, Regeneron, AstraZeneca, Celgene, Shire, and Dr. Falk Pharma for EGIDs, Blueprint Medicines for ISM, and Novartis Pharmaceuticals, Genentech, and Gossamer Bio for CU. 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 early-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 AK002 for particular indications. As a result, we may fail to capitalize on other product candidates or indications that may ultimately have proven to be more profitable.***

We are currently focusing our efforts on developing AK002 for eosinophilic gastritis (“EG”), eosinophilic gastroenteritis (“EGE”), indolent systemic mastocytosis (“ISM”), chronic urticaria (“CU”) and severe allergic conjunctivitis (“SAC”). As a result, we may forego or delay pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development activities for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target markets for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA investigation could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

**Risks Related to Regulatory Approval and Other Legal Compliance Matters**

***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. 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. Examples of such regulations include future legislation or administrative action, or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

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

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

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

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

We have completed a randomized, double-blind placebo-controlled Phase 1 trial for AK002 in 51 healthy volunteers, an open-label Phase 2 trial in 47 patients with CU, as well as a Phase 1 trial in 25 patients with ISM. We are also currently testing AK002 in a double-blind, placebo-controlled Phase 2 trial in patients with EG and in a Phase 1 trial in patients with SAC. Although we have conducted various preclinical studies and completed one Phase 1 clinical trial, we do not know the predictive value of these studies and trials for our future clinical trials, and we cannot guarantee that any positive results in preclinical studies or previous clinical trials will successfully translate to patients in our future clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical testing, and many product candidates fail in clinical trials despite promising preclinical results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. Because Siglec-8 is only naturally expressed in humans and certain other primates, there is no standard animal toxicology model for anti-Siglec-8 therapies, and the acceptability of our preclinical safety data for AK002 depends on the continued acceptance by the FDA and EMA, and the acceptance by other regulatory authorities, of the use of our proprietary transgenic mice models for toxicology studies.

AK002 has generally been well tolerated in our clinical trials. The most common adverse event has been the occurrence of mild to moderate infusion-related reactions ("IRRs") (consisting of flushing, feeling of warmth, headache, nausea or dizziness) which occurred mostly during the first infusion and diminished or did not occur on subsequent infusions. Temporal interruption of the AK002 infusion and minimal intervention generally resulted in prompt resolution of symptoms and ability to resume the infusion without further complications, although there have been instances when an IRR has resulted in a subject being discontinued from a trial. Subjects in our ongoing and planned clinical trials may in the future suffer other significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. If clinical trials of our product candidates fail to demonstrate efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, development and commercialization of our product candidates.

If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, the EMA, other applicable regulatory authorities or an institutional review board may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus 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 have completed a clinical trial in Australia and currently have an ongoing clinical trial in Germany. We may also in the future choose to conduct additional clinical trials in these countries or other countries, including in Europe. The acceptance of study data by the FDA, EMA or applicable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice and (ii) the trials are performed by clinical investigators of recognized competence and pursuant to current good clinical practices regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

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

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

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

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

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

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

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

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

Regulatory authorities in some jurisdictions, including the United States 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 United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. We have obtained orphan drug designation for EG and EGE in the United States and for ISM in the European Union. We expect to seek orphan drug designation for AK002 for other gastrointestinal diseases and may seek orphan drug designations for other indications or for other of our product candidates. There can be no assurances that we will be able to obtain such designations.

In the United States, 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 United States 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 United States 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.

***Although we may seek a breakthrough therapy designation for AK002 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 AK002 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 United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The Trump Administration and certain members of Congress have made various efforts to repeal all or portions of the Affordable Care Act ("ACA"), including suspending the penalties for failing to comply with the individual insurance mandate, removing funds designed to drive enrollment in the program and coming within a single vote in the U.S. Senate of repealing the ACA altogether. There is uncertainty with respect to the impact future actions by the Trumps Administration or Congress may have and any changes likely will take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any further healthcare reform legislation or the impact of potential legislation on us. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

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

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.

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information was made publicly available on a searchable website in September 2014 and will be disclosed on an annual basis; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

***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.

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

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

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

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

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

**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 President and Chief Executive Officer, Dr. Robert Alexander, and our Chief Financial Officer and Chief Operating Officer, Dr. Adam Tomasi, and our ability to attract and retain highly skilled executive officers and employees.***

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

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

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

We currently do not have and have never had a marketing or sales team for the marketing, sales and distribution of any of our product candidates that may be able to obtain regulatory approval. In order to commercialize any product candidates, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third-parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

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

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

At December 31, 2018, we had 62 full-time employees, including 42 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, 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 AK002 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 AK002 and any other future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of clinical management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of AK002 and any other future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize AK002 and any other future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

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

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

***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 perform our obligations under our collaborations and discover new targets.

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

As of December 31, 2018, we had gross U.S. federal and state net operating loss carryforwards of $101.2 million and $39.5 million, respectively, which expire beginning in 2032. As of December 31, 2018, the Company had federal and California research and other tax credit carryforwards of $3.8 million and $2.5 million, respectively. It is possible that we will not generate taxable income in time to use our net operating loss carryforwards before their expiration or at all. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage points change (by value) in the ownership of its equity over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. We have not yet undertaken an analysis under Sections 382 and 383 of the Internal Revenue Code to see if any of our net operating loss carryforwards were limited as a result of our prior stock stales, including those made as part of our initial public offering. As a result, we may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Accordingly, our ability to utilize our net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to our company.

**Risks Related to Intellectual Property**

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

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

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

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

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

Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our current and future licensors were the first to file any patent application related to a product candidate. Furthermore, if third-parties have filed such patent applications on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third-parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third-parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third-parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. In addition, patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including biosimilar or generic medications. For example, some of the patents that we

exclusively licensed from The Johns Hopkins University will expire in 2021, one of our owned patent families that claims one of the product candidates will expire in 2035 in the United States and similar patent applications are pending in foreign jurisdictions with a projected expiration date in 2034, at which time the underlying technology covered by such patents can be used by any third-party, including competitors. Although the patent term extensions under the Hatch-Waxman Act in the United States may be available to extend the patent term, we cannot provide any assurances that any such patent term extension will be obtained and, if so, for how long.

Due to the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent. However, the applicable authorities, including the FDA and the U.S. Patent and Trademark Office ("USPTO") in the United States, and any equivalent foreign regulatory authority, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

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

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

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

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

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

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

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

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

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

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

Our commercial success depends upon our ability, and the ability of our current and future licensors, to develop, manufacture, market and sell our product candidates and use our and our current or future licensors' wholly-owned

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

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

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

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

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

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

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. An unfavorable outcome could require us or our current and future licensors to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our current and future licensors a license on commercially reasonable terms or at all. Even if we or our current and future licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our current and future licensors. In addition, we could be found liable for monetary

damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business.

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

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

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

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

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Trade secrets can be difficult to protect. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, contract manufacturers, consultants, advisors and other third-parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of the parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent information and techniques and we cannot guarantee that our competitors will not independently develop substantially equivalent information and techniques. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us. Failure on our part to adequately protect our trade secrets and our confidential information would harm our business and our competitive position.

**Risks Related to Our Dependence on Third-Parties**

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

We do not have the ability to independently conduct our clinical trials. We currently rely on third-parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials of AK002 and expect to continue to rely upon third-parties to conduct additional clinical trials of AK002 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 current 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 AK002, our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third-parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. In the case of AK002, we rely on a single third-party manufacturer, Lonza, and we currently have no alternative manufacturer in place. We do not have long-term supply agreements and we purchase our required drug product on a purchase order basis. If we were to experience an unexpected loss of supply of AK002, or any of our other product candidates, for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. Replacement of our sole manufacturer of AK002 would result in substantial delay and interrupt our clinical trials involving AK002.

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

- the possible failure of the third-party to manufacture our product candidate according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the possible breach by the third-party contractors of our agreements with them;

- the failure of third-party contractors to comply with applicable regulatory requirements;
- the possible failure of the third-party to manufacture our product candidates according to our specifications;
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

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

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

***We may not gain the efficiencies we expect from further scale-up of manufacturing of AK002, and our third-party manufacturers may be unable to successfully scale-up manufacturing in sufficient quality and quantity for AK002 or our other product candidates, which could delay or prevent the conducting of our clinical trials or the development or commercialization of our other product candidates.***

Our third-party manufacturer, Lonza, is currently manufacturing AK002 at a scale that is sufficient for us to complete our planned clinical trials and, if we receive marketing approval, to commercialize AK002 for the indications we are currently targeting. However, we may consider increasing the batch scale to gain cost efficiencies. If Lonza is unable to scale-up the manufacture of AK002 at such time, we may not gain such cost efficiencies and may not realize the benefits that would typically be expected from further scale-up of manufacturing of AK002.

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

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

As product candidates progress through preclinical and late stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods

and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

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

Manufacturing biologics, especially in large quantities, is complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. Lonza, our current third-party manufacturer, has, and our future third-party manufacturers may have, multiple locations at which they conduct manufacturing. However, AK002 and our other product candidates are currently only being manufactured at one of Lonza's locations. If this location becomes unavailable at its anticipated capacity or the location of the manufacture of AK002 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 location. 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 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 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.

**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 IPO at $18.00 per share on July 19, 2018 and, our common stock reached a high of $65.48 per share during the fourth quarter of 2018. As of March 7, 2019 the closing price of our common stock was $37.11. The trading price of our common stock could be subject to wide fluctuations in response to various factors, which in addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, include:

- the timing and results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;

- regulatory actions with respect to our products or our competitors' products;
- 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. 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.

***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.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, partnerships and marketing, distribution or licensing arrangements. We do not have any committed external source of funds. We may also from time to time issue additional shares of common stock at a discount from the then current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common 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 operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.***

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, 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:

- 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 AK002 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 AK002 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 AK002 or any of our future product candidates;
- the level of demand for AK002 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 products candidates, if approved, and existing and potential future products that compete with AK002 and any of our future product candidates;
- our ability to commercialize AK002 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.

***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, 2018, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 77.4% of our outstanding voting stock. As a result, this group of stockholders has the ability to significantly influence all matters requiring stockholder approval, including the election of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

***We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley Act"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (ii) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

***We will likely incur significant additional costs in order to comply with the SEC rules implementing Section 404 of the Sarbanes-Oxley Act.***

We will likely incur significant additional costs in order to comply with the SEC rules implementing Section 404 of the Sarbanes-Oxley Act. Under these rules, beginning with our annual report on Form 10-K for the year ending December 31, 2019, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

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

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

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

***We may 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 may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

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

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

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

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

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

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

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

***Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

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

Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (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.

**Item 1B. Unresolved Staff Comments.**

If the registrant is an accelerated filer or a large accelerated filer, as defined in Rule 12b-2 of the Exchange Act (§240.12b-2 of this chapter), or is a well-known seasoned issuer as defined in Rule 405 of the Securities Act (§230.405 of this chapter) and has received written comments from the Commission staff regarding its periodic or current reports under the Act not less than 180 days before the end of its fiscal year to which the annual report relates, and such comments remain unresolved, disclose the substance of any such unresolved comments that the registrant believes are material. Such disclosure may provide other information including the position of the registrant with respect to any such comment.

**Item 2. Properties.**

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

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

**Item 3. Legal Proceedings.**

From time to time, we may become involved in litigation or other legal proceedings. 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, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

**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 7, 2019, there were 35 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial owners of our common stock represented by these record holders.

### Dividend Policy

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

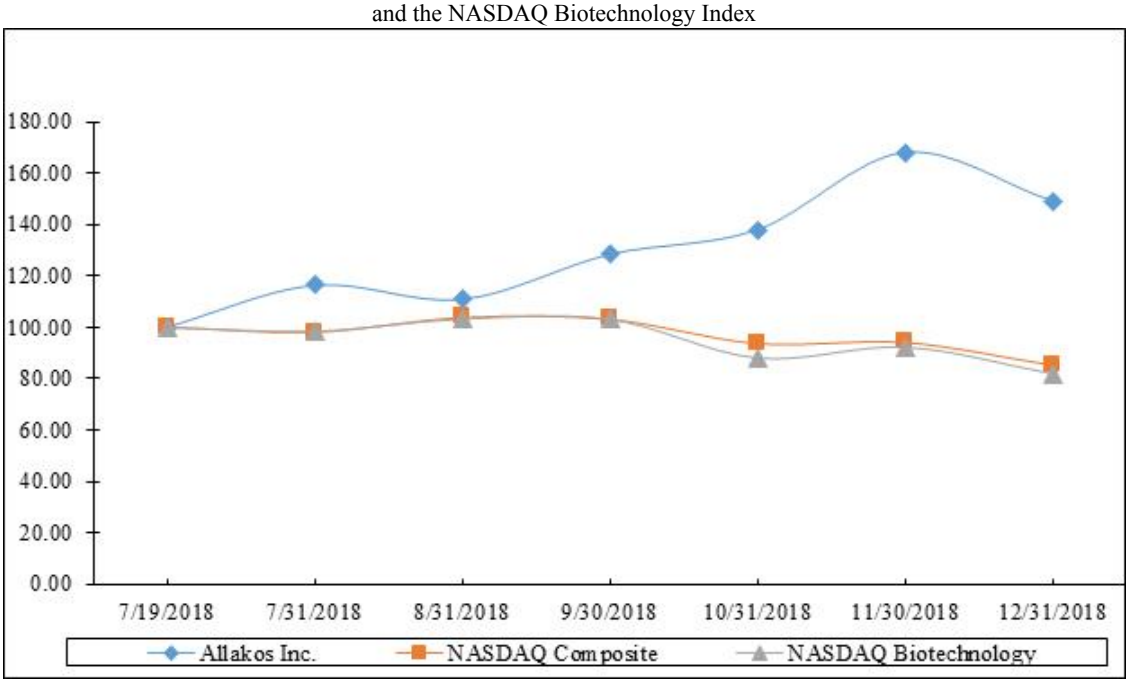
### Performance Graph

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

The following graph compares the cumulative total return to stockholder return on our common stock relative to the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. An investment of $100 is assumed to have been made in our common stock and each index on July 19, 2018 (the first day of trading of our common stock) and its relative performance is tracked through December 31, 2018. Pursuant to applicable Securities and Exchange Commission rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. The stockholder returns shown on

the graph below are based on historical results and are not indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

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




| | 7/19/2018 | 7/31/2018 | 8/31/2018 | 9/30/2018 | 10/31/2018 | 11/30/2018 | 12/31/2018 |
|---|---|---|---|---|---|---|---|
| Allakos Inc. | $ 100.00 | $ 130.46 | $ 124.29 | $ 143.97 | $ 154.72 | $ 188.51 | $ 167.26 |
| NASDAQ Composite | 100.00 | 98.05 | 103.79 | 103.06 | 93.62 | 94.08 | 85.24 |
| NASDAQ Biotechnology | 100.00 | 98.42 | 103.22 | 103.09 | 88.04 | 92.23 | 81.92 |

**Recent Sales of Unregistered Securities**

During the year ended December 31, 2018, we granted stock options to purchase an aggregate of 2,462,741 shares of common stock to certain employees under the 2012 Plan at exercise prices per share ranging from $4.01 to $16.00, for an aggregate exercise price of approximately $12.4 million.

During the year ended December 31, 2018, we issued and sold to our employees an aggregate of 526,686 shares of common stock upon the exercise of options under our 2012 Plan at exercise prices per share ranging from $0.36 to $1.16, for an aggregate exercise price of approximately $0.3 million.

On July 27, 2018, we issued an aggregate of 46,893 shares of common stock (the "Warrant Shares"), to an accredited investor upon the cashless exercise of the investor's then outstanding warrants to purchase an aggregate of 47,616 shares of common stock. The aggregate exercise price of the Warrant Shares was approximately $29,000, representing a weighted-average exercise price per share of approximately $0.61.

The offers, sales and issuances of the securities described above were exempt from registration under the Securities Act under either (1) Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or (2) Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of such securities, other than the Warrant Shares, were our employees, consultants or directors and they received the securities under our 2012 Plan. The recipient of the Warrant Shares is an accredited investor. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

**Use of Proceeds from Registered Securities**

On July 18, 2018, our Registration Statement on Form S-1 (File No. 333-225836) relating to the IPO of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 8,203,332 shares of our common stock, including 1,069,999 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a price of $18.00 per share. The aggregate offering price for shares sold in the offering was $147.7 million. Goldman Sachs & Co. LLC and Jefferies LLC acted as joint book-running managers for the offering, and William Blair & Company, L.L.C. acted as the lead manager for the offering. On July 23, 2018, we closed the sale of such shares, resulting in aggregate cash proceeds to us of approximately $133.9 million, net of underwriting discounts, commissions and offering expenses paid or payable by us. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO, as described in our final prospectus filed with the SEC on July 19, 2018 pursuant to Rule 424(b) under the Securities Act, as amended.

**Issuer Purchases of Equity Securities**

Not applicable.

**Item 6. Selected Financial Data.**

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

Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the financial and other data below in conjunction with the section titled "Management's Discussion and Analysis

of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| | (in thousands, except per share data) | | |
| **Statements of Operations Data:** | | | |
| Loss from operations | $ (45,721) | $ (22,254) | $ (17,060) |
| Net loss | $ (43,538) | $ (23,552) | $ (17,100) |
| Net loss per share, basic and diluted (1) | $ (2.20) | $ (14.54) | $ (13.03) |
| Weighted-average shares of common stock outstanding, basic and diluted (1) | 19,833 | 1,620 | 1,312 |

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| | (in thousands) | | |
| **Balance Sheet Data:** | | | |
| Cash and cash equivalents and marketable securities | $ 178,906 | $ 85,207 | $ 13,416 |
| Working capital (1) | 176,353 | 83,452 | 11,031 |
| Total assets | 191,259 | 87,029 | 14,176 |
| Total liabilities | 7,265 | 2,828 | 7,616 |
| Convertible preferred stock | — | 142,969 | 42,996 |
| Accumulated deficit | (104,112) | (60,574) | (37,022) |
| Total stockholders' equity (deficit) | 183,994 | (58,768) | (36,436) |

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

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

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

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

- *the impact that the adoption of new accounting pronouncements will have on our financial statements;*
- *the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;*
- *the timing and focus of our future clinical trials, and the reporting of data from those trials;*
- *our plans relating to commercializing AK002, if approved, including the geographic areas of focus and sales strategy;*
- *the size of the market opportunity for AK002 in each of the diseases we are targeting;*
- *the number of diseases represented in the patient population enrolled in our clinical trials, and our ability to evaluate response to treatment of AK002 in diseases other than the primary indication in our clinical trials;*
- *our estimates of the number of patients in the United States who suffer from the diseases we are targeting and the number of patients that will enroll in our clinical trials;*
- *the beneficial characteristics, safety, efficacy and therapeutic effects of AK002;*
- *the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for AK002 or our other product candidates for various diseases;*
- *our ability to obtain and maintain regulatory approval of AK002 or our other product candidates;*
- *our plans relating to the further development of AK002 and our other product candidates;*
- *existing regulations and regulatory developments in the United States and other jurisdictions;*
- *our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;*
- *our continued reliance on third-parties to conduct additional clinical trials of AK002 and our other product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;*
- *the need to hire additional personnel and our ability to attract and retain such personnel;*
- *the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;*
- *our financial performance;*
- *the sufficiency of our existing cash, cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements;*

- *our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and*
- *our anticipated use of the proceeds from our initial public offering and the concurrent private placement.*

*These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including, but not limited to, those described in "Risk Factors." In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report on Form 10-K and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled "Risk Factors" included in Part I, Item 1A and elsewhere in this Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We qualify all of the forward-looking statements in this Annual Report on Form 10-K by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.*

**Overview**

We are a clinical stage biotechnology company developing AK002, our wholly owned monoclonal antibody, for the treatment of various eosinophil and mast cell related diseases. AK002 selectively targets both eosinophils and mast cells, white blood cells that are widely distributed in the body and play a central role in the inflammatory response. Inappropriately activated eosinophils and mast cells have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. As such, AK002 has the potential to treat a large number of severe diseases. AK002 has demonstrated activity in clinical trials. In these trails, AK002 depleted blood eosinophils and improved symptoms in patients with three forms of chronic urticaria ("CU") and indolent systemic mastocytosis ("ISM"), all mast cell driven diseases. The activity observed in ISM and CU suggest that AK002 could provide significant benefit to patients suffering from these diseases and highlight AK002's potential to broadly inhibit mast cells in different disease settings. We are developing AK002 for the treatment of eosinophilic gastritis ("EG"), eosinophilic gastroenteritis ("EGE"), and eosinophilic esophagitis ("EoE"). In addition, we have or are currently conducting studies in ISM, CU, and severe allergic conjunctivitis ("SAC") and are evaluating additional indications for future development.

Despite the knowledge that eosinophils and mast cells drive many pathological conditions, there are no approved therapies that selectively target both eosinophils and mast cells. AK002 binds to Siglec-8, an inhibitory receptor found on eosinophils and mast cells, which represents a novel way to selectively deplete or inhibit these important immune cells and thereby resolve inflammation. We believe AK002 is the only Siglec-8 targeting antibody currently in clinical development and has the potential to have advantages over current treatments for the diseases we are pursuing.

Since our inception in 2012, we have devoted substantially all of our resources and efforts towards the research and development of our product candidates. We initially began developing two product candidates, AK001 and AK002, both of which are monoclonal antibodies targeting Siglec-8. These compounds entered clinical trials in 2015 and 2016, respectively. Due to the greater activity of AK002, we decided to focus our development efforts on AK002 and discontinued the development of AK001 in 2017. We have no current plans to continue development of AK001 at this time but may choose to do so in the future. 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 $43.5 million, $23.6 million and $17.1 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $104.1 million.

Our operations have been financed primarily through the private placements of convertible debt instruments and convertible preferred stock. These private placements provided gross proceeds of $146.9 million. As of December 31, 2018, we had cash, cash equivalents and marketable securities of $178.9 million, which we believe will be sufficient to fund our planned operations for at least the next 12 months from the issuance of our financial statements.

***Initial Public Offering***

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

In connection with the completion of our IPO on July 23, 2018, all then outstanding shares of convertible preferred stock converted into 30,971,627 shares of common stock.

**Components of Operating Results**

***Revenue***

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

***Operating Expenses***

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

*Research and Development Expenses*

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

- consultant and personnel-related costs including salaries, benefits, travel and stock-based compensation expense;
- costs incurred under service agreements with contract research organizations ("CROs") that conduct nonclinical and clinical research activities on our behalf;
- costs incurred under service agreements with contract development and manufacturing organizations ("CDMOs") for the manufacture and fill finish of our preclinical and clinical materials;
- 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 to laboratories;
- 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 vendors and our 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.

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 third-party CROs and CDMOs have comprised a significant portion of our research and development expenses since inception. We track external CRO and CDMO costs on a program-by-program basis following the advancement of a product candidate into clinical development. To date, we have advanced two product candidates, AK001 and AK002, into clinical development, although we discontinued the development of AK001 in 2017. Residual costs related to AK001 incurred after discontinuation in 2017 are primarily related to the winding down of historically contracted research and development activities and as such, we do not anticipate incurring significant expenses related to AK001 development in future periods. Consulting and personnel-related costs, laboratory supplies and non-capital equipment utilized in the conduct of in-house research, in-licensing fees and general overhead, are not tracked on a program-by-program basis, nor are they allocated, as they commonly benefit projects in our pipeline or span multiple programs.

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| AK002 contract research and development | $ 12,990 | $ 5,133 | $ 2,989 |
| AK001 contract research and development | 929 | 3,820 | 5,460 |
| Consulting and personnel-related costs | 14,144 | 6,033 | 3,452 |
| Other unallocated research and development costs | 5,224 | 3,520 | 2,771 |
| Total | $ 33,287 | $ 18,506 | $ 14,672 |

*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 and facility costs not otherwise included in research and development expenses. Legal costs include general corporate and patent legal fees and related costs.

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities including costs related to personnel, outside consultants, attorneys and accountants, among others. Additionally, we expect to incur incremental costs associated with operating as a public

company, including expenses related to maintaining compliance with the rules and regulations of the Securities and Exchange Commission ("SEC"), and those of any national securities exchange on which our securities are traded, additional insurance premiums, investor relations activities and other ancillary administrative and professional services.

***Interest Income (Expense), Net***

Interest income (expense), net, primarily consists of stated interest on outstanding principal amounts drawn under our historical debt facility with SVB, amortization of debt discounts and beneficial conversion feature associated with convertible notes payable to related parties and the amortization and accretion of debt discounts and deferred issuance costs associated with amounts drawn under our historical debt facility with SVB. Also included within interest income (expense), net, is interest and investment income earned on our cash, cash equivalents and marketable securities included on the balance sheets.

***Other Income (Expense), Net***

Other income (expense), net, primarily consists of charges related to the extinguishment of our historical debt facility with SVB, as well as amounts realized from gains and losses related to fluctuations in foreign currencies.

**In-Licensing Agreements**

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

We recognized $0.3 million of milestone expense for the year ended December 31, 2018 and did not recognize any milestone expense during the year ended December 31, 2017. Milestone payments are not creditable against royalties. As of December 31, 2018, we have not incurred any royalty liabilities related to our license agreements, as product sales have not yet commenced.

*Exclusive License Agreement with The Johns Hopkins University*

In December 2013, we entered into a license agreement with The Johns Hopkins University, ("JHU") for a worldwide exclusive license to develop, use, manufacture and commercialize covered product candidates including AK001 and AK002, which was amended in September 30, 2016. Under the terms of the agreement, we have made upfront and milestone payments of $0.3 million through December 31, 2018 and we may be required to make aggregate additional milestone payments of up to $4.0 million. We also issued 88,887 shares of common stock as consideration under the JHU license agreement. In addition to milestone payments, we are also subject to single-digit royalties to JHU based on future net sales of each licensed therapeutic product candidate by us and our affiliates and sublicensees, with up to a low six-digit dollar minimum annual royalty payment.

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

In October 2013, we entered into a tripartite agreement with BioWa Inc. ("BioWa"), and Lonza Sales AG ("Lonza"), for the non-exclusive worldwide license to develop and commercialize product candidates including AK002 that are manufactured using a technology jointly developed and owned by BioWa and Lonza. Under the terms of the agreement, we have made milestone payments of $0.4 million through December 31, 2018 and we may be required to make aggregate additional milestone payments of up to $41.0 million. In addition to milestone payments, we are also subject to minimum annual commercial license fees of $40,000 per year to BioWa until such time as

BioWa receives royalty payments, as well as low single-digit royalties to BioWa and to Lonza. Royalties are based on future net sales by us and our affiliates and sublicensees and vary dependent on Lonza's participation as sole manufacturer for commercial production.

**Critical Accounting Policies and Use of Estimates**

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

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

***Research and Development Expenses***

As part of the process of preparing our financial statements, we estimate our accrued research and development expenses at each balance sheet date. This process involves reviewing purchase orders and open contracts, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments as necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by CROs and CDMOs in connection with research and development activities for which we have not yet been invoiced.

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

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

***Stock-Based Compensation***

We account for stock-based compensation expense resulting from stock-based awards granted to employees and directors 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 and directors. At each subsequent reporting date, we are required to evaluate whether the achievement of any

associated vesting conditions is probable and whether or not any such events have occurred that would have resulted in the acceleration of vesting.

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

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

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

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

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

***Determination of Fair Value of Common Stock on Grant Dates prior to our IPO***

The estimated fair value of the common stock underlying our stock options was determined at each grant date by our board of directors, with input from management. All options to purchase shares of our common stock are intended to be exercisable at a price per share not less than the per-share fair value of our common stock underlying those options on the date of grant. As a private company with no active public market for our common stock, our board of directors has periodically determined the estimated per-share fair value of our common stock considering, among other things, contemporaneous valuations performed by independent valuation specialists in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, (the "Practice Aid").

The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock in order to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, our board of directors considered a number of available methods including those described below. Each of these methods requires the use of significant judgments including making assumptions regarding our future operating performance, as well as the timing and probability of future financing and liquidity events. The relative probabilities and timing surrounding each future event were determined based on an analysis of our prospects and market conditions at the time. The enterprise valuations utilized in each method were historically determined using either the guideline public company method, the similar transaction method or backsolved using a contemporaneous transaction of our convertible preferred stock. For valuations derived using the guideline public company method and similar transaction method, we focused on life science companies at similar stages of development that recently completed initial public offerings or had recently consummated a liquidation event.

Resulting valuations associated with these future scenarios were discounted back to the valuation date using an appropriate risk-adjusted discount rate. Finally, we applied discounts for lack of marketability to our common stock to account for the lack of access to an active public market. If different methodologies or assumptions were used, our stock-based compensation expense, net loss and net loss per share applicable to common stockholders could have been significantly different.

*Option-Pricing Method.* The option-pricing method ("OPM"), treats the various classes of capital stock as call options on the total equity value of a company, with exercise prices determined using thresholds for each equity value that results in a change in the allocation to each class of capital stock. Accordingly, common stock only has value if the funds available for distribution to stockholders exceeds all current and future preferred stock liquidation preferences modeled at the time of a liquidity event, such as a strategic sale, merger or disposition of the Company. In order to calculate the fair value of the various call options, the OPM incorporates the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires management to make additional assumptions such as the expected volatility of the underlying equity securities. Expected volatility utilized in our valuation models was based on the historical trading volatility of our publicly traded peer companies, which we assess for reasonableness and update on a continuous basis as necessary.

*Probability-Weighted Expected Return Method*. The probability-weighted expected return method ("PWERM"), is a scenario-based analysis that estimates value per share based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock.

*Hybrid Method*. The Hybrid Method is a blended approach using aspects of both the PWERM and OPM, in which the equity value in one of the scenarios is calculated using an OPM. In the hybrid method used by us, two types of future-event scenarios were considered: an IPO and an unspecified liquidity event.

Based on our early stage of development and other relevant factors, we determined that an OPM was the most appropriate method for allocating enterprise value for our November 2015 common stock valuation. For the common stock valuation that we performed in December 2016, we determined the PWERM to be the most appropriate as we were within twelve to eighteen months from a potential IPO. We determined the Hybrid Method to be the most appropriate for subsequent valuations performed in August 2017, December 2017 and March 2018, as our expectations around the timing and form of liquidity became better understood.

The dates of our contemporaneous valuations have not always coincided with the dates of our stock option grants. In determining the exercise prices of the stock options, our board of directors considered, among other things, the most recent contemporaneous valuations of our common stock and our assessment of additional objective and subjective factors we believed were relevant as of the grant date. The additional factors considered when determining any changes in fair value between the most recent contemporaneous valuation and the grant dates included our stage of research and development, our operating and financial performance and current business conditions.

***Determination of the fair value of our common stock on grant dates following our IPO***

The fair value of each share of common stock underlying our stock-based awards is based on the closing price of our common stock as reported by the NASDAQ Global Select Market on the date of grant.

***Income Taxes***

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

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

As of December 31, 2018, our gross deferred tax assets were $28.9 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, we have offset the total net deferred tax assets with a full valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses, ("NOLs"), which may be limited by certain rules governing changes in ownership, as defined in Section 382 of the Internal Revenue Code of 1986, as amended. Similar rules may apply under state tax laws. Our ability to use our remaining NOLs may be further limited if we experience future ownership changes.

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

***Recent Accounting Pronouncements***

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

***JOBS Act***

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), was enacted. Section 107 of the JOBS Act provides that an emerging growth company ("EGC"), can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenues of $1.07 billion or more, (ii) the date on which we are deemed to be a "large accelerated filer" under the rules of the SEC with at least $700.0 million of outstanding equity securities held by non-affiliates, (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the previous three years or (iv) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO .

**Results of Operations**

***Comparison of the Years Ended December 31, 2018, 2017 and 2016***

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Operating expenses | | | |
| Research and development | $ 33,287 | $ 18,506 | $ 14,672 |
| General and administrative | 12,434 | 3,748 | 2,388 |
| Total operating expenses | 45,721 | 22,254 | 17,060 |
| Loss from operations | (45,721) | (22,254) | (17,060) |
| Interest income (expense), net | 2,375 | (1,302) | (51) |
| Other income (expense), net | (192) | (287) | 11 |
| Loss before benefit from income taxes | (43,538) | (23,843) | (17,100) |
| Benefit from income taxes | — | (291) | — |
| Net loss | (43,538) | (23,552) | (17,100) |
| Unrealized loss on marketable securities, net of tax | (15) | — | — |
| Comprehensive loss | $ (43,553) | $ (23,552) | $ (17,100) |

*Research and Development Expenses*

Research and development expenses were $33.3 million for the year ended December 31, 2018 compared to $18.5 million for the year ended December 31, 2017, an increase of $14.8 million. The increase in research and development expenses was attributable to an additional $8.1 million in consulting and personnel-related costs resulting primarily from our increased employee headcount, $7.9 million of incremental AK002 contract research and development costs attributable to the expansion of our clinical development efforts including our Phase 2 trials in patients with EG and CU and our Phase 1 trial in patients with SAC, and an increase of $1.7 million in other unallocated research and development costs primarily related to the conduct of in-house research, including activities supporting the continued development of antibodies in our pipeline. The increases were partially offset by a period-over-period decrease of $2.9 million in AK001 contract research and development costs as a result of our discontinuation of AK001 development efforts during the year ended December 31, 2017. Residual costs incurred during the year ended December 31, 2018 were related to the winding down of historically contracted research and development activities.

Research and development expenses were $18.5 million for the year ended December 31, 2017 compared to $14.7 million for the year ended December 31, 2016, an increase of $3.8 million. The increase in research and development expenses was primarily attributable to an additional $2.6 million in consulting and personnel-related costs resulting primarily from our increased employee headcount, as well as $2.1 million of incremental AK002 contract research and development costs, primarily attributable to the production of clinical material during the year ended December 31, 2017. Further increases of $0.7 million in other unallocated research and development costs were primarily related to the conduct of in-house research, including activities supporting the continued development of antibodies in our pipeline Increases were offset by a year-over-year decrease of $1.6 million in AK001 contract research and development costs as a result of our discontinuation of AK001 development efforts during the year ended December 31, 2017.

*General and Administrative Expenses*

General and administrative expenses were $12.4 million for the year ended December 31, 2018 compared to $3.7 million for the year ended December 31, 2017, an increase of $8.7 million. The increase in general and administrative expenses was primarily attributable to an additional $6.6 million in personnel-related costs as a result of our increase in employee headcount, as well as $0.8 million of incremental expense incurred from outside professional service providers for legal, information technology, and investor relations activities associated with becoming a publicly traded company in July 2018. Additionally, we incurred incremental facilities and other

administrative costs of $1.3 million, such as general business insurance premiums, not otherwise included in research and development expenses.

General and administrative expenses were $3.7 million for the year ended December 31, 2017 compared to $2.4 million for the year ended December 31, 2016, an increase of $1.3 million. The increase in general and administrative expenses was primarily attributable to an additional $1.1 million in personnel-related costs as a result of our increase in employee headcount, as well as an additional $0.2 million in other allocated costs.

*Interest Income (Expense), Net*

Interest income (expense), net, was $2.4 million for the year ended December 31, 2018 compared to $(1.3) million for the year ended December 31, 2017. The period-over-period change of $3.7 million was attributable to increased interest income of $2.4 million earned on capital raised by our Series B preferred stock financing and IPO in November 2017 and July 2018, respectively, along with decreased interest expense of $1.3 million resulting from the repayment and termination of our historical debt facility and conversion of our convertible promissory notes payable to related parties during the year ended December 31, 2017.

Interest income (expense), net was $(1.3) million for the year ended December 31, 2017 compared to $(0.1) million for the year ended December 31, 2016. The period-over-period change of $1.2 million was primarily attributable to increased interest expense of $1.1 million associated with convertible promissory notes payable to related parties that were outstanding during the year ended December 31, 2017, as well as additional interest expense of $0.2 million associated with our debt facility with SVB.

*Other Income (Expense), Net*

There were no significant period-over-period changes in other income (expense), net, for the years ended December 31, 2018 and 2017.

*Provision for (Benefit from) Income Taxes*

There was no benefit from income taxes during the year ended December 31, 2018.

Benefit from income taxes was $0.3 million for the year ended December 31, 2017, which was solely attributable to the intra-period tax accounting effect related to the beneficial conversion feature associated with our convertible promissory notes payable to related parties. See Note 7 to our financial statements. We did not record a benefit from income taxes for the year ended December 31, 2016.

**Liquidity and Capital Resources**

***Sources of Liquidity***

We are a clinical stage biotechnology company with a limited operating history. As a result of our significant research and development expenditures, we have generated net losses since our inception. Prior to completing our IPO, we historically financed our operations primarily through the private placement of convertible preferred stock. These private placements provided gross proceeds of $146.9 million. We also had a debt facility with SVB, for an aggregate of $5.0 million, which was fully repaid and terminated during 2017.

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

As of December 31, 2018, we had cash, cash equivalents and marketable securities of $178.9 million.

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

***Summary Cash Flows***

***Comparison of the Years Ended December 31, 2018, 2017 and 2016***

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, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Net cash used in operating activities | $ (38,450) | $ (22,568) | $ (17,578) |
| Net cash used in investing activities | (151,047) | (264) | (234) |
| Net cash provided by financing activities | 138,752 | 94,623 | 24,012 |
| Net increase (decrease) in cash, cash equivalents and restricted cash | $ (50,745) | $ 71,791 | $ 6,200 |

*Cash Used in Operating Activities*

Net cash used in operating activities was $38.5 million for the year ended December 31, 2018, which was primarily attributable to our net loss of $43.5 million adjusted for net noncash charges of $3.4 million and net changes in operating assets and liabilities of $1.6 million. Noncash charges included $4.6 million in stock-based compensation expense and $0.2 million in depreciation and amortization expense, partially offset by $1.3 million in net amortization of premiums and discounts on marketable securities and $0.1 million accretion of tenant improvement allowances.

Net cash used in operating activities was $22.6 million for the year ended December 31, 2017, which was primarily attributable to our net loss of $23.6 million. Cash used in operating activities included a net decrease of $0.7 million in operating assets and liabilities, offset by non-cash charges related to the amortization of the beneficial conversion feature associated with convertible promissory notes payable to related parties of $0.9 million, stock-based compensation of $0.4 million, depreciation and amortization of $0.2 million, stated interest on convertible promissory notes payable to related parties of $0.2 million and our loss on extinguishment of debt of $0.2 million.

Net cash used in operating activities was $17.6 million for the year ended December 31, 2016, which was primarily attributable to our net loss of $17.1 million. Cash used in operating activities included a net decrease of $0.8 million in operating assets and liabilities, offset by non-cash charges related to stock-based compensation of $0.2 million and depreciation and amortization of $0.1 million.

*Cash Used in Investing Activities*

Net cash used in investing activities was $151.0 million for the year ended December 31, 2018, which consisted of $236.6 million for the purchases of marketable securities and $6.9 million for the purchases of property and equipment, partially offset by $92.5 million for maturities of marketable securities.

Net cash used in investing activities was $0.3 million for the year ended December 31, 2017, which was entirely attributable to purchases of property and equipment.

Net cash used in investing activities was $0.2 million for the year ended December 31, 2016, which was entirely attributable to purchase of property and equipment.

*Cash Provided by Financing Activities*

Net cash provided by financing activities was $138.8 million for the year ended December 31, 2018, which consisted primarily of $138.4 million in proceeds from the issuance of common stock, $0.3 million in proceeds received from employees for the exercise of stock options and $0.1 million in proceeds from the repayment of recourse promissory notes.

Net cash provided by financing activities was $94.6 million for the year ended December 31,2017, which was primarily the result of $92.3 million of net proceeds received from private placements of our convertible preferred stock, as well as $7.4 million of net proceeds received from the issuance of convertible promissory notes payable to

related parties and $0.2 million of net proceeds from the exercise of employee stock options. Cash used in financing activities included $5.3 million of repayments of historical debt facility with SVB.

Net cash provided by financing activities was $24.0 million for the year ended December 31,2016, which was primarily the result of $19.0 million of net proceeds received from private placements of our convertible preferred stocks as well as $5.0 million of borrowings drawn as part of our historical debt facility with SVB.

***Funding Requirements***

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise funding through private or public equity or debt financings, or other sources such as strategic collaborations. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies.

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

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

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

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

**Contractual Obligations and Commitments**

The following table outlines our contractual obligations and commitments at December 31, 2018 (in thousands):

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 Year | 1-3 Years | 3-5 Years | More than 5 Years |
| Operating lease obligations (1) | $ 13,867 | $ 403 | $ 2,504 | $ 2,656 | $ 8,304 |
| Purchase obligations (2) | 15,604 | 15,604 | — | — | — |
| Total | $ 29,471 | $ 16,007 | $ 2,504 | $ 2,656 | $ 8,304 |

(1) Operating lease obligations represent future minimum lease payments due under our current facility lease.
(2) Purchase obligations represent noncancelable minimum service fees due to counterparties under various master service agreements.

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

**Off-Balance Sheet Arrangements**

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

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

***Interest Rate Sensitivity***

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

***Foreign Currency Sensitivity***

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

**Item 8. Financial Statements and Supplementary Data.**

**ALLAKOS INC.**
**INDEX TO FINANCIAL STATEMENTS**

## Report of Independent Registered Public Accounting Firm

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

**Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Allakos Inc. (the Company) as of December 31, 2018 and 2017, the related statements of operations and comprehensive loss, statements of convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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.

/s/ Ernst & Young LLP

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

Redwood City, California

March 14, 2019

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

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 33,660 | $ 85,207 |
| Investments in marketable securities | 145,246 | — |
| Prepaid expenses and other current assets | 2,703 | 1,037 |
| Total current assets | 181,609 | 86,244 |
| Property and equipment, net | 8,848 | 445 |
| Other long-term assets | 802 | 340 |
| Total assets | $ 191,259 | $ 87,029 |
| **Liabilities, convertible preferred stock and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,092 | $ 1,703 |
| Accrued expenses and other current liabilities | 3,164 | 1,089 |
| Total current liabilities | 5,256 | 2,792 |
| Other long-term liabilities | 2,009 | 36 |
| Total liabilities | 7,265 | 2,828 |
| Commitments and contingencies (Note 7) | | |
| Series A convertible preferred stock, $0.001 par value per share; no shares and 26,083 shares authorized as of December 31, 2018, and 2017, respectively; no shares and 20,866 shares issued and outstanding as of December 31, 2018 and 2017, respectively; aggregate liquidation preference of $0 and $46,950 as of December 31, 2018 and 2017, respectively | — | 42,996 |
| Series B convertible preferred stock, $0.001 par value per share; no shares and 12,632 shares authorized as of December 31, 2018 and, 2017, respectively; no shares and 10,105 shares issued and outstanding as of December 31, 2018 and 2017, respectively; aggregate liquidation preference of $0 and $100,141 as of December 31, 2018 and 2017, respectively | — | 99,973 |
| Stockholders' equity (deficit): | | |
| Preferred stock, $0.001 par value per share; 20,000 and no shares authorized as of December 31, 2018 and 2017, respectively; no shares issued and outstanding as of December 31, 2018 and 2017 | — | — |
| Common stock, $0.001 par value per share; 200,000 and 55,000 shares authorized as of December 31, 2018 and 2017, respectively; 42,117 and 2,114 shares issued and outstanding as of December 31, 2018 and 2017, respectively | 42 | 3 |
| Additional paid-in capital | 288,079 | 1,803 |
| Accumulated other comprehensive loss | (15) | — |
| Accumulated deficit | (104,112) | (60,574) |
| Total stockholders’ equity (deficit) | 183,994 | (58,768) |
| Total liabilities, convertible preferred stock and stockholders’ equity (deficit) | $ 191,259 | $ 87,029 |

*See accompanying notes to financial statements*

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Operating expenses | | | |
| Research and development | $ 33,287 | $ 18,506 | $ 14,672 |
| General and administrative | 12,434 | 3,748 | 2,388 |
| Total operating expenses | 45,721 | 22,254 | 17,060 |
| Loss from operations | (45,721) | (22,254) | (17,060) |
| Interest income (expense), net | 2,375 | (1,302) | (51) |
| Other income (expense), net | (192) | (287) | 11 |
| Loss before benefit from income taxes | (43,538) | (23,843) | (17,100) |
| Provision for (benefit from) income taxes | — | (291) | — |
| Net loss | (43,538) | (23,552) | (17,100) |
| Unrealized loss on marketable securities, net of tax | (15) | — | — |
| Comprehensive loss | $ (43,553) | $ (23,552) | $ (17,100) |
| Net loss per common share: | | | |
| Basic and diluted | $ (2.20) | $ (14.54) | $ (13.03) |
| Weighted-average number of common shares outstanding: | | | |
| Basic and diluted | 19,833 | 1,620 | 1,312 |

*See accompanying notes to financial statements*

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

| | Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | |
| **Balance as of December 31, 2015** | 12,422 | $ 22,210 | 1,565 | $ 2 | $ 322 | $ — | $ (19,922) | $ (19,598) |
| Issuance of Series A convertible preferred stock for cash, net of issuance costs of $8 | 8,444 | 18,991 | — | — | — | — | — | — |
| Reclassification of preferred stock tranche liability upon issuance of Series A convertible preferred stock | — | 1,795 | — | — | — | — | — | — |
| Stock-based compensation expense | — | — | — | — | 182 | — | — | 182 |
| Issuance of common stock warrants in connection with debt facility | — | — | — | — | 24 | — | — | 24 |
| Issuance of common stock upon exercise of stock options | — | — | 40 | — | 20 | — | — | 20 |
| Vesting of restricted common stock | — | — | — | — | 36 | — | — | 36 |
| Net loss | — | — | — | — | — | — | (17,100) | (17,100) |
| **Balance as of December 31, 2016** | 20,866 | $ 42,996 | 1,605 | $ 2 | $ 584 | $ — | $ (37,022) | $ (36,436) |
| Issuance of Series B convertible preferred stock for cash, net of issuance costs of $168 | 9,334 | 92,331 | — | — | — | — | — | — |
| Issuance of Series B convertible preferred stock upon conversion of convertible promissory notes | 771 | 7,642 | — | — | — | — | — | — |
| Stock-based compensation expense | — | — | — | — | 402 | — | — | 402 |
| Repurchase of unvested restricted common stock | — | — | (34) | — | — | — | — | — |
| Issuance of common stock upon exercise of stock options | — | — | 543 | 1 | 227 | — | — | 228 |
| Vesting of restricted common stock | — | — | — | — | 28 | — | — | 28 |
| Recognition of beneficial conversion feature related to convertible promissory notes payable to related parties, net of $966 tax benefit | — | — | — | — | 1,867 | — | — | 1,867 |
| Reclassification of beneficial conversion feature related to convertible promissory notes payable to related parties, net of $675 tax expense | — | — | — | — | (1,305) | — | — | (1,305) |
| Net loss | — | — | — | — | — | — | (23,552) | (23,552) |
| **Balance as of December 31, 2017** | 30,971 | $ 142,969 | 2,114 | $ 3 | $ 1,803 | $ — | $ (60,574) | $ (58,768) |
| Proceeds from repayment of recourse promissory note | — | — | — | — | 50 | — | — | 50 |
| Conversion of preferred stock upon initial public offering | (30,971) | (142,969) | 30,972 | 30 | 142,939 | — | — | 142,969 |
| Issuance of common stock upon initial public offering, net of offering costs of $3,466 | — | — | 8,453 | 8 | 138,349 | — | — | 138,357 |
| Stock-based compensation expense | — | — | — | — | 4,570 | — | — | 4,570 |
| Issuance of common stock upon exercise of stock options | — | — | 531 | 1 | 344 | — | — | 345 |
| Issuance of common stock upon exercise of warrants | — | — | 47 | — | — | — | — | — |
| Vesting of restricted common stock | — | — | — | — | 24 | — | — | 24 |
| Unrealized loss on marketable securities, net of tax | — | — | — | — | — | (15) | — | (15) |
| Net loss | — | — | — | — | — | — | (43,538) | (43,538) |
| **Balance as of December 31, 2018** | — | $ — | 42,117 | $ 42 | $ 288,079 | $ (15) | $ (104,112) | $ 183,994 |

*See accompanying notes to financial statements*

**ALLAKOS INC.**
**STATEMENTS OF CASH FLOWS**
**(in thousands)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2018** | **2017** | **2016** |
| **Cash flows from operating activities** | | | |
| Net loss | $ (43,538) | $ (23,552) | $ (17,100) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Stock-based compensation | 4,570 | 402 | 182 |
| Net amortization of premiums and discounts on marketable securities | (1,310) | — | — |
| Amortization of beneficial conversion feature related to convertible promissory notes payable to related parties | — | 853 | — |
| Benefit from deferred income taxes | — | (291) | — |
| Depreciation and amortization | 242 | 241 | 148 |
| Noncash interest related to convertible promissory notes payable to related parties | — | 228 | — |
| Loss on extinguishment of debt facility | — | 159 | — |
| Noncash interest related to debt facility | — | 101 | 29 |
| Accretion of tenant improvement allowance | (82) | — | — |
| Changes in operating assets and liabilities: | | | |
| Prepaid expenses and other current assets | (1,489) | (637) | 275 |
| Other long-term assets | 313 | (150) | (250) |
| Accounts payable | 76 | 510 | (1,141) |
| Accrued expenses and other current liabilities | 2,063 | (432) | 279 |
| Other long-term liabilities | 705 | — | — |
| Net cash used in operating activities | (38,450) | (22,568) | (17,578) |
| **Cash flows from investing activities** | | | |
| Purchases of marketable securities | (236,601) | — | — |
| Proceeds from maturities of marketable securities | 92,500 | — | — |
| Purchases of property and equipment | (6,946) | (264) | (234) |
| Net cash used in investing activities | (151,047) | (264) | (234) |
| **Cash flows from financing activities** | | | |
| Proceeds from issuance of common stock, net of issuance costs | 138,357 | — | — |
| Proceeds from issuance of convertible preferred stock, net of issuance costs | — | 92,331 | 18,991 |
| Proceeds from issuance of convertible promissory notes, net of issuance costs | — | 7,414 | — |
| Repayment of debt facility | — | (5,250) | — |
| Proceeds from debt facility, net of issuance costs | — | — | 4,985 |
| Proceeds from exercise of stock options, net of repurchases | 345 | 228 | 36 |
| Payments for deferred financing costs | — | (100) | — |
| Proceeds from repayment of recourse promissory note | 50 | — | — |
| Net cash provided by financing activities | 138,752 | 94,623 | 24,012 |
| Net increase (decrease) in cash, cash equivalents and restricted cash | (50,745) | 71,791 | 6,200 |
| Cash, cash equivalents and restricted cash, beginning of period | 85,207 | 13,416 | 7,216 |
| Cash, cash equivalents and restricted cash, end of period | $ 34,462 | $ 85,207 | $ 13,416 |
| **Supplemental disclosures** | | | |
| Cash paid for interest | $ — | $ 228 | $ 39 |
| Noncash investing and financing items: | | | |
| Conversion of convertible promissory notes payable to related parties | $ — | $ 7,642 | $ — |
| Recognition of beneficial conversion feature related to convertible promissory notes to related parties, net of benefit for income taxes | $ — | $ 1,867 | $ — |
| Reclassification of preferred stock tranche liability upon settlement | $ — | $ — | $ 1,795 |
| Lessor funded lease incentives included in property and equipment | $ 1,386 | $ — | $ — |
| Reclassification of beneficial conversion feature related to convertible promissory notes payable to related parties, net of tax expense | $ — | $ 1,305 | $ — |
| Property and equipment purchased in accounts payable | $ 313 | $ 89 | $ — |
| Deferred initial public offering costs in accounts payable | $ — | $ 63 | $ — |
| Vesting of restricted common stock subject to repurchase | $ 24 | $ 28 | $ 20 |
| Issuance of common stock warrants in connection with debt facility | $ — | $ — | $ 24 |

*See accompanying notes to financial statements*

## 1. Organization and Business

Allakos Inc. ("Allakos" or the "Company") was incorporated in the state of Delaware in March 2012. Allakos is a clinical stage biopharmaceutical company focused on the development of AK002 for the treatment of eosinophil and mast cell related diseases. The Company's primary activities to date have included establishing its facilities, recruiting personnel, conducting research and development of its product candidates and raising capital. The Company's operations are located in Redwood City, California.

### *Liquidity Matters*

Since inception, the Company has incurred net losses and negative cash flows from operations. During the year ended December 31, 2018, the Company incurred a net loss of $43.5 million and used $38.5 million of cash in operations. As of December 31, 2018, the Company had an accumulated deficit of $104.1 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 and issuance of convertible preferred stock. Management expects to incur additional operating losses in the future as the Company continues to further develop, seek regulatory approval for and, if approved, commence commercialization of its product candidates. The Company had $178.9 million of cash, cash equivalents and marketable securities at December 31, 2018. 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.

### *Initial Public Offering and Related Transactions*

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

In connection with the completion of the IPO on July 23, 2018, all then outstanding shares of convertible preferred stock were converted into 30,971,627 shares of common stock.

Upon the completion of the IPO, the Company's certificate of incorporation was amended and restated. Under the amended and restated certificate of incorporation, the Company's authorized capital stock consists of 200,000,000 shares of common stock with a par value $0.001 per share and 20,000,000 shares of convertible preferred stock with a par value $0.001 per share.

### *Reverse Stock Split*

On July 6, 2018, the Company amended its certificate of incorporation to effect a 1-for-1.25 reverse stock split of every outstanding share of its convertible preferred stock and common stock. The Company's audited financial statements and accompanying notes for the years ended December 31, 2017 and 2016 on the Company's Second Amendment to its Registration Statement No. 333-225836, filed with the Securities and Exchange Commission ("SEC") on July 17, 2018, have been retroactively restated to reflect the reverse stock split.

## 2. Summary of Significant Accounting Policies

### *Basis of Presentation*

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

***Use of Estimates***

Management uses significant judgment when making estimates related to common stock valuation and related stock-based compensation expense, accrued expenses related to clinical trials and deferred tax valuation allowances. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates under different assumptions or conditions, and those differences could be material to the financial position and results of operations.

***Concentration of Credit Risk and Other Risks and Uncertainties***

Financial instruments that potentially subject the Company to credit risk principally consist of cash, cash equivalents and marketable securities. These financial instruments are held in accounts at select financial institutions that management believes possess high credit quality. Amounts on deposit with these financial institutions 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 U.S. 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, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Cash and cash equivalents | $ 33,660 | $ 85,207 | $ 13,416 |
| Restricted cash | 802 | — | — |
| Total | $ 34,462 | $ 85,207 | $ 13,416 |

Restricted cash at December 31, 2018 represents $0.8 million in deposits restricted from withdrawal and held by a bank in the form of collateral for an irrevocable standby letter of credit held as security for the lease of the Company's facility in Redwood City, California. Restricted cash amounts are included within long term assets on the Company's balance sheets.

***Marketable Securities***

The Company invests in marketable securities, primarily securities issued by the U.S. government and its agencies. Investments with contractual maturities greater than 90 days that mature less than one year from the balance sheet date are classified as short-term investments. Those investments with a contractual maturity date greater than one year are considered long-term investments. Unrealized gains and losses are excluded from earnings and are reported as a component of accumulated comprehensive income (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 (expense), net, on the statements of operations and comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on investments in marketable securities are included in other income (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.

***Deferred Initial Public Offering Costs***

Costs incurred in connection with the IPO primarily consist of direct incremental legal, printing and accounting fees. IPO costs are capitalized as incurred and will be offset against proceeds upon consummation of the offering. In the event the offering had been terminated or abandoned, deferred IPO costs would have been expensed in the period such determination had been made. As of December 31, 2017, there was $0.2 million of deferred IPO costs included in other long-term assets on the Company's balance sheets. The Company completed its IPO in July 2018. Accordingly, there were no deferred IPO offering costs at December 31, 2018.

***Lease Liabilities***

The Company classifies the agreements for its office and laboratory facilities as an operating lease. Rent expense is recorded on a straight-line basis over the term of the lease. Differences that exist between cash rent payments and the recognition of rent expense, such as those resulting from rent abatements or contractual escalations of minimum lease payments, are recorded as a deferred rent liability and recognized as adjustments to rental expense on a straight-line basis over the term of the lease. The current portion of the deferred rent liability is included within accrued expenses and other current liabilities on the Company's balance sheets. Noncurrent portion of deferred rent liability is classified as other long-term liabilities. Tenant improvement allowances received are recorded as lease incentive obligations included in accrued expenses and other current liabilities and other long-term liabilities on the Company's balance sheets and are amortized to rent expense over the term of the lease.

***Term Loan Financing Costs***

During the year ended December 31, 2017, the Company recognized noncash interest expense of $101,000, related to its then outstanding debt facility. Noncash interest included the amortization and accretion of various costs incurred in connection with the issuance of the associated debt instruments and calculated using the effective interest rate method over the expected term of the debt. In December 2017, the Company repaid all outstanding debt. Noncash interest expense was included in interest income (expense), net, within the Company's statements of operations and comprehensive loss.

***Property and Equipment, Net***

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

Laboratory equipment – 3 to 5 years

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

Upon retirement or sale, the cost of disposed assets and their related accumulated depreciation are removed from the balance sheet. Any resulting gains or losses on dispositions of property and equipment are included as a component of other 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.

***Research and Development Expense***

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

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

***Accrued Research and Development Costs***

Service agreements with contract research organizations ("CROs") and contract development and manufacturing organizations ("CDMOs") comprise a significant component of the Company's research and development activities. External costs for CROs and CDMOs 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 CROs, CDMOs 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 CRO, CDMO or other outside service provider, the payments are recorded within prepaid expenses and other current assets and subsequently recognized as research and development expense when the associated services have been performed. As actual costs become known, the Company adjusts its liabilities and assets. Inputs, such as the extent of services received and the duration of services to be performed, may vary from the Company's estimates, which will result in adjustments to research and development expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. The Company's historical estimates have not been materially different from actual amounts recorded.

***Convertible Debt Features***

Beneficial conversion features embedded within the Company's convertible debt instruments are recognized at their intrinsic value at the commitment date. Intrinsic value is calculated as the difference between the effective conversion price and the fair value of the preferred stock into which the debt is convertible, multiplied by the number of shares of preferred stock into which the debt is convertible. The Company allocates a portion of the proceeds from issuance of the convertible debt to the beneficial conversion feature as a reduction to the carrying value of the debt, with the offset to additional paid-in capital. The resulting debt discount is amortized to interest expense through the stated maturity date of the convertible debt instrument using the effective interest method. Conversion of the debt to convertible preferred stock is accounted for as an extinguishment. Upon conversion, all unamortized discounts at the conversion date are recognized immediately as interest expense. The Company then allocates a portion of the reacquisition price to the repurchase of the beneficial conversion feature, as calculated by the intrinsic value of the conversion option at the extinguishment date. The residual amount, if any, is allocated to the convertible debt instrument. The gain or loss on extinguishment of the convertible debt instrument is measured as the difference between the retired debt's reacquisition price and carrying amount prior to extinguishment. Gains or losses resulting from convertible debt instruments issued to related parties are classified as capital contributions or distributions.

***Preferred Stock Tranche Rights***

Convertible preferred stock that includes features the Company has determined are not clearly and closely related to the equity host are bifurcated and accounted for separately as freestanding derivative assets or liabilities on the balance sheet at their estimated fair value. The Company historically recorded preferred stock derivative liabilities resulting from certain investors' rights to purchase from the Company, on the same terms as the Series A Preferred Stock Purchase Agreement executed in December 2012, additional shares of Series A convertible preferred stock in a second and third tranche. At initial recognition, the Company recorded these derivatives as an asset or liability on the balance sheets at their estimated fair value. The derivatives were subject to remeasurement at each balance sheet date, with changes in fair value recognized as a component of other income (expense), net on the Company's statements of operations and comprehensive loss. At the time of each tranche funding, the Company remeasured the derivative asset or liability, with the change in fair value recognized as a component of other income (expense), net and then reclassified the remaining value associated with the preferred stock derivative to Series A convertible preferred stock.

***Convertible Preferred Stock***

The Company recorded all shares of convertible preferred stock net of offering costs at their respective fair values on the dates of issuance. The convertible preferred stock was recorded outside of stockholders' deficit because, in the event of certain deemed liquidation events considered not solely within the Company's control, such as a merger, acquisition or sale of all or substantially all of the Company's assets, the convertible preferred stock will become redeemable at the option of the holders. In the event of a change of control of the Company, proceeds received from the sale of such shares will be distributed in accordance with the liquidation preferences set forth in the Company's Second Amended and Restated Certificate of Incorporation unless the holders of convertible preferred stock had previously converted their shares of convertible preferred stock into shares of common stock. In connection with the completion of the Company's IPO in July 2018, all then outstanding shares of convertible preferred stock were converted into 30,971,627 shares of common stock.

***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 payments to employees and directors to be recognized as expense in the statements of operations and comprehensive loss based on their grant date fair values. For purposes of determining the estimated fair value of stock options granted to employees and directors, the Company uses the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the input of certain assumptions that involve judgment, for which changes can materially affect the resulting estimates of fair value. The assumptions used to determine the fair value of stock options granted were as follows:

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

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

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

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

The 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 on a straight-line basis over the requisite service period, which is generally the vesting period.

***Income Taxes***

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

***Comprehensive Loss***

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

***Net Loss per Share***

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

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Numerator: | | | |
| Net loss | $ (43,538) | $ (23,552) | $ (17,100) |
| Denominator: | | | |
| Weighted-average shares of common stock outstanding, basic and diluted | 19,833 | 1,620 | 1,312 |
| Net loss per share, basic and diluted | $ (2.20) | $ (14.54) | $ (13.03) |

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, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Series A convertible preferred stock | — | 20,866 | 20,866 |
| Series B convertible preferred stock | — | 10,105 | — |
| Options to purchase common stock | 7,811 | 4,884 | 2,722 |
| Warrants to purchase common stock | — | 48 | 48 |
| Unvested restricted common stock | 47 | 104 | 205 |
| Shares issuable under 2018 Employee Stock Purchase Plan | 29 | — | — |
| Total | 7,887 | 36,007 | 23,841 |

***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.

***Recent Accounting Pronouncements***

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2018-13, *Fair Value Measurement* (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement. This ASU eliminates, modifies and adds disclosure requirements for fair value measurements. The amendments in this ASU are effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the effects of this ASU on its financial statements and related disclosures.

In August 2018, the SEC adopted amendments to certain disclosure requirements in the Securities Act Release No. 33-10532, *Disclosure Update and Simplification*. Under the amendments, the Company must provide an analysis of changes in each caption of stockholders' equity presented in the balance sheet in a note or separate statement. The Company will adopt the amendments beginning with the first quarter of fiscal year 2019. The Company does not expect the adoption of this standard to have a material impact on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which generally requires lessees to recognize operating and financing lease liabilities and corresponding right-of-use assets on the balance sheet along with enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from such leasing arrangements. Subsequently, in July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which includes a transition method for companies adopting ASU 2016-02 through the recognition of a cumulative-effect adjustment to the opening balance of accumulated deficit or retained earnings in the period of adoption. The Company plans to adopt both standards effective January 1, 2019 using a modified retrospective approach, taking advantage of certain practical expedients permitted under the transition guidance. Practical expedients the Company plans to elect include (i) carrying forward historical lease classifications, (ii) foregoing a re-evaluation of historical contracts to identify embedded leases, (iii) foregoing a re-assessment of initial direct costs related to leases that existed prior to adoption, (iv) combining lease and non-lease components, and (v) recognizing lease expense for all contracts with an initial term of 12 months or less within the statements of operations and comprehensive loss on a straight-line basis over the requisite lease term. The Company has not yet completed an assessment of the total impact such adoption will have on the Company’s financial statements and related disclosures but expects to record a right-of-use asset and a corresponding liability for the lease of its corporate headquarters during the period of adoption.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows: Restricted Cash* (“ASU 2016-18”). ASU 2016-18 amends the classification and presentation of changes in restricted cash or restricted cash equivalents in the statement of cash flows. ASU 2016-18 is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company retrospectively adopted ASU 2016-18 effective January 1, 2018. There was no significant impact to the Company’s financial statements as there were no restricted cash or restricted cash equivalent balances in the prior periods.

**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, 2018 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash equivalents | | | | |
| Money market funds | $ 31,555 | $ — | $ — | $ 31,555 |
| Total cash equivalents | $ 31,555 | $ — | $ — | $ 31,555 |
| Marketable securities | | | | |
| U.S. treasuries | $ 145,246 | $ — | $ — | $ 145,246 |
| Total marketable securities | $ 145,246 | $ — | $ — | $ 145,246 |
| Total cash equivalents and marketable securities | $ 176,801 | $ — | $ — | $ 176,801 |

| | December 31, 2017 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash equivalents | | | | |
| Money market funds | $ 82,526 | $ — | $ — | $ 82,526 |
| Total cash equivalents | $ 82,526 | $ — | $ — | $ 82,526 |

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, 2018 and 2017.

**4. Marketable Securities**

All marketable securities were considered available-for-sale at December 31, 2018. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's marketable securities by major security type at December 31, 2018 are summarized in the table below (in thousands):

| | December 31, 2018 | | | |
|---|---|---|---|---|
| | Amortized Cost Basis | Unrealized Gains | Unrealized Losses | Fair Value |
| Marketable securities | | | | |
| U.S. treasuries | $ 145,261 | $ — | $ (15) | $ 145,246 |
| Total | $ 145,261 | $ — | $ (15) | $ 145,246 |

The Company had no other-than-temporary impairments on its marketable securities during the year ended December 31, 2018. The Company has the intent and ability to hold all marketable securities until their maturities.

The Company held no marketable securities at December 31, 2017.

**5. Balance Sheet Components and Supplemental Disclosures**

***Property and Equipment, Net***

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

| | December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Laboratory equipment | $ 3,272 | $ 949 |
| Furniture and office equipment | 1,666 | — |
| Leasehold improvements | 4,545 | 55 |
| | 9,483 | 1,004 |
| Less accumulated depreciation | (635) | (559) |
| Property and equipment, net | $ 8,848 | $ 445 |

Depreciation and amortization expense for the years ended December 31, 2018, 2017 and 2016 was $0.2 million, $0.2 million and $0.1 million, respectively.

***Accrued Expenses and Other Current Liabilities***

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

| | December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Accrued outside professional services | $ 1,964 | $ 787 |
| Accrued compensation and benefits | 1,041 | 265 |
| Lease incentive obligation, current | 123 | — |
| Other current liabilities | 36 | 37 |
| Total | $ 3,164 | $ 1,089 |

**6. Debt Facility**

In June 2016, the Company entered into a Loan and Security Agreement with a financial institution, providing for term loans to the Company, in two tranches for an aggregate principal amount of $5.0 million. Interest on the term loans was calculated at a floating per annum rate equal to the prime rate reported in The Wall Street Journal plus one quarter of one percent (0.25%). Upon execution of the agreement, the Company had immediate access to borrow up to $2.5 million in principal. The remaining $2.5 million in principal would be made available to the Company on or prior to December 31, 2016, subject to the satisfaction of certain borrowing conditions including the achievement of certain pre-defined clinical development milestones. In July 2016, the Company drew down an initial term loan of $2.5 million. Subsequently, in December 2016, the Company drew down the remaining $2.5 million term loan. During 2017 this debt facility was fully repaid and terminated.

The Company incurred upfront costs of $15,000 to issue the debt facility which were classified as a discount to the carrying value of the term loans included on the balance sheet at December 31, 2016. Final payments due to the lender for facility fees of $0.2 million were treated as deferred issuance costs and accreted to interest expense over the term of the loans. Amortization of the upfront issuance costs and accretion of the deferred issuance costs was calculated using the effective interest method.

***Common Stock Warrants***

As part of the Loan and Security Agreement, the Company also agreed to issue the financial institution warrants to purchase shares of its common stock upon each draw of the term loans. During the year ended December 31, 2016, the Company issued the financial institution warrants to purchase a total of 47,616 shares of common stock at a weighted average exercise price of $0.61 per share. The common stock warrants were immediately exercisable upon issuance and shall remain outstanding for a period of ten years from the date of issuance. Fair value of the common stock warrants totaling $24,000 was recorded as a reduction to the carrying value of the loans and amortized to interest expense over the remaining term of the loans using the effective interest method. The initial fair value of the warrants was determined using the Black-Scholes option pricing model including weighted average assumptions for expected volatility of 80.0%, an expected life equal to the contractual term of the warrants of 10 years and a risk-free interest rate of 2.0%. During the year ended December 31, 2018, all outstanding warrants were exercised by cashless exercise, resulting in the Company's issuance of 46,893 shares of common stock.

***Loss on Extinguishment***

In December 2017, the Company repaid the term loans prior to the stated maturity date, recognizing a loss on extinguishment of debt totaling $0.2 million. This amount consisted of a $50,000 prepayment penalty, a write-off of $17,000 of unamortized discount and a write-off of $92,000 of unamortized debt issuance costs. The loss on extinguishment of debt was recorded as other income (expense), net on the statements of operations and comprehensive loss. The write-offs of unamortized discount and unamortized debt issuance costs represent a non-cash adjustment to reconcile net income to net cash used in operating activities on the statement of cash flows.

**7. Commitments and Contingencies**

***Operating Lease Obligations***

The Company's operating lease obligations primarily relate to leased office and laboratory space under noncancelable operating leases. During the year ended December 31, 2018, the Company terminated the lease agreement for its San Carlos, California office. As of December 31, 2018, the Company's remaining lease agreement pertains to its corporate headquarters located in Redwood City, California. The lease agreement was entered into during January 2018 and includes a contractual lease term commencing upon substantial completion and delivery of the premises which occurred in November 2018. The base term of the lease is 10.75 years and includes an option to extend an additional term of 5 years. The lease agreement required a security deposit of $0.8 million, which the Company satisfied by establishing a letter of credit secured by restricted cash. Restricted cash is recorded in other long-term assets on the Company's balance sheet.

The lease agreement allows for a tenant improvement allowance of up to $1.4 million to be applied to the total cost of tenant improvements to the leased premises. Tenant improvement allowances received are recorded as leasehold improvements with corresponding lease incentive obligations included in accrued expenses and other current liabilities and other long-term liabilities on the Company's balance sheets. Leasehold improvements are depreciated and lease incentive obligations are amortized to rent expense over the term of the lease. As of December 31, 2018, unamortized lease incentive obligations totaled $1.3 million.

In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance and repair costs. Rent expense is recognized using the straight-line method over the respective terms. The Company records a deferred rent liability calculated as the difference between rent expense and cash rental payments. The current portion of the liability is included within accrued expenses and other current liabilities on the Company's balance sheets. The remaining non-current portion is classified in other long-term liabilities.

Future minimum lease payments required under operating leases are as follows (in thousands):

| Fiscal Year Ending December 31, | | |
|---|---|---|
| 2019 | $ | 403 |
| 2020 | | 1,233 |
| 2021 | | 1,271 |
| 2022 | | 1,308 |
| 2023 | | 1,348 |
| Thereafter | | 8,304 |
| Total minimum future lease payments | $ | 13,867 |

Net rent expense was $1.0 million, $0.5 million and $0.4 for the years ended December 31, 2018, 2017 and 2016, respectively.

***Purchase Obligations***

The Company has entered into contractual agreements with various research and development organizations and suppliers in the normal course of its business. All contracts are terminable, with varying provisions regarding termination. If a contract were to be terminated, the Company would only be obligated for the products or services that the Company had received through the time of termination as well as any non-cancelable minimum payments contractually agreed upon prior to the effective date of termination. In the case of terminating a clinical trial agreement with an investigational site conducting clinical activities on behalf of the Company, the Company would also be obligated to provide continued support for appropriate safety procedures through completion or termination of the associated study. As of December 31, 2018, the Company had $15.6 million of non-cancelable purchase obligations under these agreements.

***In-Licensing Agreements***

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

The Company recognized $0.3 million, zero and $0.3 million of milestone expense for the years ended December 31, 2018, 2017 and 2016, respectively. Milestone payments are not creditable against royalties. As of December 31, 2018, the Company has not incurred any royalty liabilities related to its license agreements, as product sales have not yet commenced.

*Exclusive License Agreement with The Johns Hopkins University*

In December 2013, the Company entered into a license agreement with The Johns Hopkins University ("JHU") for a worldwide exclusive license to develop, use, manufacture and commercialize covered product candidates including AK001 and AK002, which was amended in September 30, 2016. Under the terms of the agreement, the Company has made upfront and milestone payments of $0.3 million through December 31, 2018 and may be required to make aggregate additional milestone payments of up to $4.0 million. The Company also issued 88,887 shares of common stock as consideration under the JHU license agreement. In addition to milestone payments, the Company is also subject to single-digit royalties to JHU based on future net sales of each licensed therapeutic product candidate by the Company and its affiliates and sublicensees, with up to a low six-digit dollar minimum annual royalty payment.

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

In October 2013, the Company entered into a tripartite agreement with BioWa Inc. ("BioWa"), and Lonza Sales AG ("Lonza"), for the non-exclusive worldwide license to develop and commercialize product candidates including

AK002 that are manufactured using a technology jointly developed and owned by BioWa and Lonza. Under the terms of the agreement, the Company has made milestone payments of $0.4 million through December 31, 2018 and may be required to make aggregate additional milestone payments of up to $41.0 million. In addition to milestone payments, the Company is also subject to minimum annual commercial license fees of $40,000 per year to BioWa until such time as BioWa receives royalty payments, as well as low single-digit royalties to BioWa and to Lonza. Royalties are based on future net sales by the Company and its affiliates and sublicensees and vary dependent on Lonza's participation as sole manufacturer for commercial production.

***Indemnification Agreements***

The Company has entered into indemnification agreements with certain directors and officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, no such matters have arisen and the Company does not believe that the outcome of any claims under indemnification arrangements will have a material adverse effect on its financial positions, results of operations or cash flows. Accordingly, the Company has not recorded a liability related to such indemnifications at December 31, 2018.

**8. Convertible Promissory Notes Payable to Related Parties, Net**

In August 2017, the Company entered into a note purchase agreement with existing investors as related parties to raise proceeds of up to $15.0 million via the issuance of convertible promissory notes (the "Notes"). The Notes bore interest at 6% per annum and were subject to automatic conversion upon a subsequent qualified financing event. Additional terms included within the note purchase agreement included an option at the election of the holder, upon maturity, to convert all outstanding principal and accrued interest into Series A convertible preferred stock at a fixed price per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization. The Company determined this option represented a beneficial conversion feature ("BCF") at the date of issuance as the fair value of the securities into which the Notes were convertible upon maturity was greater than the effective conversion price on the date of issuance.

During the year ended December 31, 2017, the Company issued $7.5 million in Notes. The Company recorded the Notes at the principal amount received, net of transaction costs of $86,000, with a portion of the proceeds being allocated to the BCF relative to its intrinsic value of $2.8 million. The Company calculated the intrinsic value of the BCF as the difference between the fair value of the underlying Series A convertible preferred stock and the effective conversion price embedded in the Notes. The BCF was initially recorded as an increase to additional paid-in capital with the offset recorded as a discount on the Notes.

During the year ended December 31, 2017, in addition to stated interest of $0.1 million, the Company recognized non-cash interest expense of $0.9 million associated with the amortization of the discounts, issuance costs and BCF. The amortization schedule was calculated using the effective interest method through August 2018, the contractual maturity of the Notes.

In November 2017, the Notes were redeemed contemporaneously with the Company's Series B convertible preferred stock financing. The aggregate of the outstanding principal and accrued interest balance of $7.6 million was converted into 771,083 shares of Series B convertible preferred stock based on the Series B convertible preferred stock fair value. The redemption of the Notes was accounted for as a debt extinguishment with a portion of the reacquisition price allocated to the BCF and total unamortized debt discount of $60,000 written off to interest expense. The amount allocated to reacquire the BCF was measured using the intrinsic value of the conversion option at the extinguishment date and reflected as a reduction to equity. As a result, the amount allocated to reacquire the Notes was less than the carrying value of the Notes which resulted in a deemed capital contribution received from related parties of $0.9 million.

***Benefit from Income Taxes Related to Intra-Period Tax Allocations***

The BCF associated with the convertible promissory notes to related parties resulted in a temporary difference between the carrying amount and tax basis of the debt instruments. Upon issuance, the Company recognized the temporary difference as a deferred tax liability of $1.0 million with an offsetting adjustment to additional paid in capital. Recognition of the deferred tax liability resulted in a reduction to the Company's net deferred tax assets.

Accordingly, the Company reduced its existing valuation allowance by $1.0 million and recognized a corresponding income tax benefit of $1.0 million in accordance with ASC 740-10, *Accounting for Uncertainty in Income Taxes.* During the year ended December 31, 2017, the deferred tax liability was reduced in relation to the amortization of the BCF. Upon extinguishment of the Notes in November 2017, the Company wrote down the remaining $0.7 million of deferred tax liability resulting in a net benefit from income taxes of $0.3 million for the year then ended.

**9. Convertible Preferred Stock and Stockholders' Equity (Deficit)**

The Company's amended and restated certificate of incorporation filed on July 23, 2018 authorizes the issuance of a total of 220,000,000 shares of stock. Of these shares, 200,000,000 are designated as common stock and 20,000,000 are designated as preferred stock. There were 42,116,641 shares of common stock issued and outstanding and no shares of preferred stock issued and outstanding at December 31, 2018.

***Convertible Preferred Stock***

In December 2012, the Company entered into a Series A Preferred Stock Purchase Agreement (the "Series A Purchase Agreement") with investors under which the Company agreed to sell and investors agreed to purchase up to 14,222,218 shares of Series A convertible preferred stock at a purchase price of $2.25 per share. Upon execution of the Series A Purchase Agreement, the Company issued 4,444,441 shares of Series A convertible preferred stock for net cash proceeds of $9.8 million (the "Initial Closing").

In August 2014, the Company and its investors amended the Series A Purchase Agreement, pursuant to which the Company agreed to sell and investors agreed to purchase up to an additional 4,444,446 shares of Series A convertible preferred stock under the same terms as the original agreement. From August 2014 through September 2014, the Company issued 6,666,662 shares of Series A convertible preferred stock at a purchase price of $2.25 per share for net cash proceeds of $14.9 million (the "Second Closings").

In March 2015, the Company and its investors amended the Series A Purchase Agreement a second time, pursuant to which the Company agreed to sell and investors agreed to purchase up to an additional 2,222,229 shares of Series A convertible preferred stock under the same terms as the original agreement. Concurrent with the second amendment, the Company issued 1,310,906 shares of Series A convertible preferred stock at a purchase price of $2.25 per share for net cash proceeds of $2.9 million (the "Additional Second Closings").

In January 2016, the Company issued 8,444,440 shares of Series A convertible preferred stock at a purchase price of $2.25 per share for net cash proceeds of $19.0 million (the "Third Closings").

In November 2017, the Company entered into a Series B Preferred Stock Purchase Agreement (the "Series B Purchase Agreement") with existing as well as new investors for the issuance of up to 10,105,181 shares of Series B convertible preferred stock at a purchase price of $9.91 per share. Upon the execution of the Series B Purchase Agreement, the Company issued 9,334,098 shares of Series B convertible preferred stock for net cash proceeds of $92.3 million. In addition, the Company issued 771,083 shares of Series B convertible preferred stock upon the conversion of outstanding convertible promissory notes to related parties, including accrued interest, in the amount of $7.6 million. See Note 8 — Convertible Promissory Notes Payable to Related Parties, Net.

As of December 31, 2017, convertible preferred stock consisted of the following (in thousands):

| | Shares Authorized | Shares Issued and Outstanding | Net Carrying Value | Aggregate Liquidation Preference |
|---|---|---|---|---|
| Series A convertible preferred stock | 26,083 | 20,866 | $ 42,996 | $ 46,950 |
| Series B convertible preferred stock | 12,632 | 10,105 | 99,973 | 100,141 |
| Total | 38,715 | 30,971 | $ 142,969 | $ 147,091 |

Prior to the conversion of the Company's convertible stock upon the Company's IPO, the significant provisions of each series of convertible preferred stock were as follows:

*Dividends* – Holders of shares of convertible preferred stock were entitled to receive noncumulative dividends prior to, and in preference to any declaration or payment of any dividend on the common stock at the rate of 8% of the original issue price of the applicable series of convertible preferred stock, when and if declared by the Company's Board of Directors. After payment of dividends to the holders of shares of convertible preferred stock, any additional dividends were to be paid equally among the holders of convertible preferred stock and common stock on an as converted basis. As of December 31, 2017 and 2016, and through the date of conversion, no dividends had been declared.

*Liquidation Preference* – In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of Series B convertible preferred stock were entitled to receive, prior and in preference to any distribution from the assets of the Company to the holders of Series A convertible preferred stock or common stock, a per-share amount equal to the sum of the original issue price of Series B convertible preferred stock plus all accrued but unpaid dividends. After the payment of the full Series B liquidation preference, holders of the Series A convertible preferred stock were entitled to receive, prior and in preference to any distribution from the assets of the Company to the holders of common stock, a per-share amount equal to the sum of the original issue price of Series A convertible preferred stock plus all accrued but unpaid dividends. After the payment of all preferential amounts required to be paid upon liquidation to the holders of the convertible preferred stock, the remaining assets would have been distributed to holders of the common stock on a pro-rata basis.

*Conversion* – Shares of convertible preferred stock were convertible at the holder's option into shares of common stock, on a share-for-share basis, using a conversion rate determined by dividing the original issue price by the conversion price. The conversion rate could be adjusted upon certain events and for certain dilutive issuances, splits and combinations. The initial conversion price for the Series A and Series B convertible preferred stock was $2.25 and $9.91, respectively. Each share of convertible preferred stock would have been automatically converted into common stock, at its then applicable conversion rate, upon (i) the closing of an underwritten public offering of the Company's common stock that provides not less than $50 million of gross proceeds at an offering price of not less than $9.91 per share of common stock, as adjusted for recapitalization or (ii) the written request for conversion by the holders of at least a majority of the convertible preferred stock, voting together on an as converted basis.

*Voting Rights* – Each share of convertible preferred stock had the same voting rights as the number of shares of common stock into which it was convertible and voted together with the holders of common stock as a single class.

*Protective Provisions* – The holders of convertible preferred stock had certain protective provisions. As long as one million shares of convertible preferred stock remained outstanding, the Company could not, without the approval of the holders of more than 50% of the then-outstanding shares of convertible preferred stock, voting as a single class on an as-converted basis, (i) authorize or create any new class or series of equity security that is senior to or on parity with the convertible preferred stock, (ii) increase or decrease the authorized number of shares under the Company's equity incentive plans, (iii) consummate a liquidation, dissolution or winding up of the Company, or any deemed liquidation event, (iv) redeem, purchase or otherwise acquire shares of common stock, subject to certain exceptions, (v) change the authorized number of directors, (vi) pay or declare dividends, or (vii) alter or change the rights, preferences or privileges of the convertible preferred stock in a manner that adversely affects their rights, preferences or privileges. In addition, the holders of Series B convertible preferred stock had certain incremental protective provisions. As long as one million shares of Series B convertible preferred stock remained outstanding, the Company could not, without the approval of the holders of at least 60% of the then-outstanding shares of Series B convertible preferred stock, voting as a single class on an as-converted basis, (i) increase or decrease the authorized number of Series B convertible preferred stock, or (ii) amend the Company's certificate of incorporation in a manner that adversely affects the rights, powers, preferences and other terms of the Series B convertible preferred stock, but does not so affect the Series A convertible preferred stock.

In connection with the completion of the Company's IPO in July 2018, all the then-outstanding shares of convertible preferred stock were converted into 30,971,627 shares of common stock and the related carrying value was reclassified to common stock and additional paid-in capital.

***Common Stock***

In April 2014, the Company issued to JHU 88,887 shares of common stock as consideration for intellectual property rights received by the Company under an exclusive license agreement with JHU executed in December 2013. The Company determined the fair value of the common stock was more readily determinable than the fair value of the services rendered. The fair value of the underlying common stock on the date of issuance was $0.39 per share, resulting in total stock compensation expense of $34,000 recognized immediately in accordance with the terms of the agreement, which provided that the shares were fully vested and nonforfeitable at the time of issuance. See Note 7 — Commitments and Contingencies.

Common shares reserved for future issuance upon the exercise, issuance or conversion of the respective equity instruments are as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Series A convertible preferred stock | — | 26,083 |
| Series B convertible preferred stock | — | 12,632 |
| Stock options issued and outstanding | 7,811 | 4,884 |
| Stock options available for future grant | 2,785 | 2,346 |
| Conversion of common stock warrants | — | 48 |
| Shares issuable under 2018 Employee Stock Purchase Plan | 500 | — |
| Total | 11,096 | 45,993 |

Common stockholders are entitled to dividends if and when declared by the Board of Directors subject to the prior rights of preferred stockholders. As of December 31, 2018 and 2017, no dividends on common stock had been declared by the Board of Directors.

**10. Stock-Based Compensation**

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Research and development | $ 1,792 | $ 175 | $ 108 |
| General and administrative | 2,778 | 227 | 74 |
| Total | $ 4,570 | $ 402 | $ 182 |

No income tax benefits for stock-based compensation expense have been recognized for the years ended December 31, 2018, 2017 and 2016 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 December 2012, the Company adopted the 2012 Equity Incentive Plan (the "2012 Plan"), as amended and restated, under which it reserved 8,455,045 shares of common stock for the issuance 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, 2017, there were 2,345,748 shares available for the Company to grant under the 2012 Plan.

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, stock appreciation rights and other stock-based awards. The 2018 Plan became effective on the business day immediately prior to the effective date of the registration statement. The Company initially reserved 4,000,000 shares of common stock for issuance under the 2018 Plan. The number of shares of common stock that may be issued under the 2018 Plan will automatically increase on each January 1, beginning with the fiscal year ending December 31, 2019, equal to the least of (i) 5,000,000 shares, (ii) 5% of the outstanding shares of common stock as of the last day of the preceding fiscal year and (iii) such other amount as the Board of Directors may determine. Stock options 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 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, 2018, there were 1,325,900 shares available for the Company to grant under the 2018 Plan and the maximum number of shares that may be added to the 2018 Plan pursuant to the preceding clause is 6,485,177 shares.

The following weighted-average assumptions were used to calculate the fair value of stock-based awards granted to employees and directors during the periods indicated:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Risk-free interest rate | 2.79% | 1.83% | 1.64% |
| Expected volatility | 73.47% | 77.59% | 73.22% |
| Expected dividend yield | — | — | — |
| Expected term (in years) | 6.01 | 6.08 | 6.02 |

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

| | Options Outstanding | Weighted-Average Exercise Price | Weighted-Average Remaining Years | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Balance at December 31, 2017 | 4,884 | $ 0.67 | 8.7 | $ 16,331 |
| Granted | 3,789 | 17.19 | | |
| Exercised | (531) | 0.65 | | |
| Forfeited | (331) | 2.62 | | |
| Balance at December 31, 2018 | 7,811 | $ 8.60 | 8.2 | $ 342,292 |
| Options exercisable | 3,684 | $ 1.02 | 7.0 | $ 188,812 |
| Options vested and expected to vest | 7,770 | $ 8.57 | 8.2 | $ 340,773 |

The weighted-average fair value of options granted to employees and directors during the years ended December 31, 2018, 2017 and 2016 was $11.05, $0.54 and $0.34 per share, respectively.

The aggregate fair value of stock options that vested during the years ended December 31, 2018, 2017 and 2016 was $1.8 million, $0.2 million and $0.2 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. Following the IPO, the aggregate intrinsic value represents the value of the Company's closing stock price on the last trading day of the year in excess of the weighted-average exercise price multiplied by the number of options outstanding or exercisable. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2018, 2017 and 2016 was $ 2.0 million, $0.1 million and $12,000, respectively.

The weighted-average remaining contractual life of options outstanding was 8.2 years and 8.7 years at December 31, 2018 and 2017, respectively. As of December 31, 2018, the weighted-average remaining contractual life was 7.0 years and 8.2 years for exercisable options and vested and expected to vest options, respectively.

During the years ended December 31, 2018 and 2017, the Company did not grant any stock options with performance-based or market-based vesting conditions, nor did the Company grant any stock options to non-employees in exchange for services.

As of December 31, 2018, total unrecognized stock-based compensation expense relating to unvested stock options was $38.2 million. This amount is expected to be recognized over a weighted-average period of 3.6 years.

***2018 Employee Stock Purchase Plan***

In July 2018, the Company's Board of Directors and stockholders approved the 2018 Employee Stock Purchase Plan (the "2018 ESPP"). There are 500,000 shares of common stock initially reserved for issuance under the 2018 ESPP. The number of shares of common stock that may be issued under the 2018 ESPP will automatically increase on each January 1, beginning with the fiscal year ending December 31, 2019, equal to the least of (i) 1,000,000 shares, (ii) 1% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year and (iii) such other amount determined by the 2018 ESPP administrator. Under the 2018 ESPP, employees may purchase shares of the Company's common stock at a price per share equal to 85% of the lower of the fair market value of the common stock on the first trading day of the offering period or on the exercise date. The 2018 ESPP provides for consecutive, overlapping 24-month offering periods, each of which will include purchase periods. The first offering period commenced on July 18, 2018 and will end on the first trading day on or before August 15, 2020. The second offering period will commence on the first trading day on or after February 15, 2019. During the year ended December 31, 2018, stock-based compensation related to the 2018 ESPP was $0.2 million. As of December 31, 2018, total unrecognized compensation expense relating to shares to be purchased under ESPP was $0.8 million over a weighted-average period of 0.9 years.

The following weighted-average assumptions were used to calculate the fair value of ESPP shares during the year ended December 31, 2018:

| | |
|---|---|
| Risk-free interest rate | 2.42% |
| Expected volatility | 65.92% |
| Expected dividend yield | — |
| Expected term (in years) | 1.24 |

***Restricted Common Stock***

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

A summary of the restricted common stock activity during the year ended December 31, 2018 is as follows (in thousands, except per share data):

| | Number of Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Balance at December 31, 2017 | 104 | $ 0.43 |
| Vested | (57) | $ 0.43 |
| Repurchased | — | $ — |
| Balance at December 31, 2018 | 47 | $ 0.43 |

The fair value of restricted common stock that vested during the years ended December 31, 2018 and 2017 was $24,000 and $28,000, respectively.

As of December 31, 2018, total liabilities related to unvested shares of restricted common stock was $20,000. This amount is expected to be recognized over a weighted-average period of 0.8 years.

**11. Income Taxes**

The Company's deferred income tax assets include operating losses and tax credit carryforwards, as well as certain temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Total deferred income tax assets, net of valuation allowance, at December 31, 2018 and 2017 were as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Deferred tax assets | | |
| Net operating loss carryforwards | $ 24,091 | $ 15,769 |
| Research and development credits | 3,995 | 2,242 |
| Accruals and reserves | 871 | 50 |
| Fixed and intangible assets | — | 51 |
| Total deferred tax assets | $ 28,957 | $ 18,112 |
| Deferred tax liabilities | | |
| Fixed and intangible assets | $ 65 | $ — |
| Total deferred tax liabilities | $ 65 | $ — |
| Net deferred tax assets before valuation allowance | 28,892 | 18,112 |
| Less: Valuation allowance | (28,892) | (18,112) |
| 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 $28.9 million and $18.1 million has been established at December 31, 2018 and 2017, respectively. The change in the valuation allowance was $10.8 million and $0.7 million for the years ended December 31, 2018 and 2017, respectively. The Company has incurred net operating losses ("NOL") since inception. As of December 31, 2018, the Company had federal and state NOL carryforwards of $101.2 million and $39.5 million, respectively, which expire beginning in 2032. As of December 31, 2018, the Company had federal and California research and other tax credit carryforwards of $3.8 million and $2.5 million, respectively. The federal tax credits expire beginning in 2033. The California tax credits can be carried forward indefinitely.

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

The effective tax rate for the years ended December 31, 2018 and 2017 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, | |
|---|---|---|
| | 2018 | 2017 |
| Federal statutory tax rate | 21.0% | 34.0% |
| Change in deferred tax asset valuation allowance | (24.8)% | (3.0)% |
| State taxes, net of federal benefit | 0.9% | 0.6% |
| Research and development tax credits | 3.3% | 1.4% |
| Remeasurement of deferreds | — | (31.2)% |
| Beneficial conversion feature | — | 1.2% |
| Other | (0.4)% | (1.8)% |
| Effective tax rate | — | 1.2% |

***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, | |
|---|---|---|
| | 2018 | 2017 |
| Balance at the beginning of the year | $ 1,149 | $ 758 |
| Increase related to current year tax positions | 678 | 359 |
| Increase related to prior year tax positions | — | 32 |
| Balance at the end of the year | $ 1,827 | $ 1,149 |

If recognized, gross unrecognized tax benefits would not have an impact on the Company's effective tax rate due to the Company's full valuation allowance position. While it is often difficult to predict the final outcome of any particular uncertain tax position, the Company does not believe that the amount of gross unrecognized tax benefits will change significantly in the next twelve months.

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, 2018 or 2017. 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.

***Benefit from Income Taxes Related to Intra-Period Tax Allocations***

The beneficial conversion feature associated with the Company's August 2017 issuance of convertible promissory notes to related parties resulted in a temporary difference between the carrying amount and tax basis of the debt instruments. Upon issuance, the Company recognized the temporary difference as a deferred tax liability of $1.0 million with an offsetting adjustment to additional paid in capital. Recognition of the deferred tax liability resulted in a reduction to the Company's net deferred tax assets. Accordingly, the Company reduced its existing valuation allowance by $1.0 million and recognized a corresponding income tax benefit of $1.0 million in accordance with ASC 740-10. During the year ended December 31, 2017, the deferred tax liability was reduced in relation to the amortization of the beneficial conversion feature. Upon extinguishment of the notes in November 2017, the Company wrote down the remaining $0.7 million of deferred tax liability resulting in a net benefit from income taxes of $0.3 million for the year ended December 31, 2017.

***Recent Changes to U.S. Tax Law***

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

**12. Defined Contribution Plans**

In July 2013, the Company established a Savings Incentive Match Plan (the "SIMPLE IRA plan") for its employees, allowing for both employee and employer contributions for those employees who meet defined minimum age and service requirements. The SIMPLE IRA plan allows participants to defer a portion of their annual compensation on a pretax basis. During the years ended December 31, 2017 and 2016, the Company made contributions to the SIMPLE IRA plan of $0.1 million and $59,000, respectively.

In January 2018, the Company terminated and replaced the SIMPLE IRA with 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 year ended December 31, 2018, the Company made contributions to the 401(k) plan of $0.3 million.

**13. Selected Quarterly Financial Data (Unaudited)**

The following tables summarize the Company's quarterly results for the years ended December 31, 2018 and 2017 (in thousands, except per share data):

| | Quarter Ended | | | |
|---|---|---|---|---|
| **2018** | **March 31, 2018** | **June 30, 2018** | **September 30, 2018** | **December 31, 2018** |
| Loss from operations | $ (8,709) | $ (9,524) | $ (11,975) | $ (15,513) |
| Net loss | $ (8,485) | $ (9,377) | $ (11,148) | $ (14,528) |
| Net loss per common share, basic and diluted | $ (4.19) | $ (4.17) | $ (0.34) | $ (0.35) |

| | Quarter Ended | | | |
|---|---|---|---|---|
| **2017** | **March 31, 2017** | **June 30, 2017** | **September 30, 2017** | **December 31, 2017** |
| Loss from operations | $ (4,977) | $ (4,598) | $ (6,233) | $ (6,446) |
| Net loss | $ (5,056) | $ (4,692) | $ (5,920) | $ (7,884) |
| Net loss per common share, basic and diluted | $ (3.56) | $ (3.18) | $ (3.60) | $ (4.08) |

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

None.

**Item 9A. Controls and Procedures.**

***Evaluation of Disclosure Controls and Procedures***

As of December 31, 2018, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as 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.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2018, the design and operation of our disclosure controls and procedures were effective at the reasonable assurance level.

***Management's Annual Report on Internal Control over Financial Reporting***

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

***Changes in Internal Control over Financial Reporting***

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fourth quarter of 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

None.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to regulation 14A, or the Proxy Statement, which proxy statement is expected to be filed with Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2018.

### Item 11. Executive Compensation.

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

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

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

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

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

### Item 14. Principal Accounting Fees and Services.

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

## PART IV

**Item 15. Exhibits, Financial Statement Schedules.**

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

(1) Financial Statements

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

(2) Financial Statement Schedules

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

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

| Exhibit Number | Description | Incorporated by Reference | | | |
|---|---|---|---|---|---|
| | | Form | File No. | Number | Filing Date |
| 3.1 | Amended and Restated Certificate of Incorporation of the Registrant. | 8-K | 001-38582 | 3.1 | 7/24/2018 |
| 3.2 | Amended and Restated Bylaws of the Registrant. | 8-K | 001-38582 | 3.2 | 7/24/2018 |
| 4.2 | Specimen common stock certificate of the Registrant. | S-1/A | 333-225836 | 4.2 | 7/09/2018 |
| 10.1+ | Form of Indemnification Agreement between the Registrant and each of its directors and executive officers. | S-1 | 333-225836 | 10.1+ | 6/22/2018 |
| 10.2+ | 2012 Equity Incentive Plan, as amended, and forms of agreement thereunder. | S-1 | 333-225836 | 10.2+ | 6/22/2018 |
| 10.3+ | 2018 Equity Incentive Plan and forms of agreements thereunder. | S-1/A | 333-225836 | 10.3+ | 7/09/2018 |
| 10.4+ | 2018 Employee Stock Purchase Plan. | S-1/A | 333-225836 | 10.4 | 7/09/2018 |
| 10.5+ | Employment Letter between the Registrant and Robert Alexander, Ph.D. | S-1/A | 333-225836 | 10.5+ | 7/09/2018 |
| 10.6+ | Employment Letter between the Registrant and Adam Tomasi, Ph.D. | S-1/A | 333-225836 | 10.6+ | 7/09/2018 |
| 10.7+ | Employment Letter between the Registrant and Henrik Rasmussen, M.D., Ph.D. | S-1/A | 333-225836 | 10.7+ | 7/09/2018 |
| 10.9+ | Executive Incentive Compensation Plan. | S-1 | 333-225836 | 10.9+ | 6/22/2018 |
| 10.10+ | Outside Director Compensation Policy. | S-1/A | 333-225836 | 10.10+ | 7/09/2018 |
| 10.11+ | Change in Control and Severance Policy. | S-1/A | 333-225836 | 10.11+ | 7/09/2018 |
| 10.12 | Lease Agreement between the Registrant and Westport Office Park, LLC, dated January 4, 2018, as amended. | S-1 | 333-225836 | 10.12 | 6/22/2018 |
| 10.14# | Non-exclusive License Agreement between the Registrant, BioWa, Inc. and Lonza Sales AG, dated October 31, 2013. | S-1/A | 333-225836 | 10.14# | 7/17/2018 |
| 10.15# | Amended and Restated Exclusive License Agreement between the Registrant and the Johns Hopkins University, dated September 30, 2016. | S-1/A | 333-225836 | 10.15# | 7/17/2018 |

| | |
|---|---|
| 23.1* | Consent of Independent Registered Public Accounting Firm. |
| 31.1* | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1** | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2** | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

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* Filed herewith.
** 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, 2019

By: /s/ Robert Alexander

**Robert Alexander, Ph.D.**
**President and Chief Executive Officer**

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

| Name | Title | Date |
|---|---|---|
| /s/ Robert Alexander<br>**Robert Alexander, Ph.D.** | President, Chief Executive Officer and Director<br>*(Principal Executive Officer)* | March 14, 2019 |
| /s/ Adam Tomasi<br>**Adam Tomasi, Ph.D.** | Chief Operating Officer, Chief Financial Officer and Secretary<br>*(Principal Financial and Accounting Officer)* | March 14, 2019 |
| /s/ Daniel Janney<br>**Daniel Janney** | Chair of the Board | March 14, 2019 |
| /s/ Robert Andreatta<br>**Robert Andreatta** | Director | March 14, 2019 |
| /s/ Steve James<br>**Steve James** | Director | March 14, 2019 |
| /s/ John McKearn<br>**John McKearn, Ph.D.** | Director | March 14, 2019 |
| /s/ Paul Walker<br>**Paul Walker** | Director | March 14, 2019 |

**Exhibit 23.1**

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-226247) pertaining to the 2018 Equity Incentive Plan, the 2018 Employee Stock Purchase Plan and the 2012 Equity Incentive Plan of Allakos Inc. of our report dated March 14, 2019, with respect to the financial statements of Allakos Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Redwood City, California
March 14, 2019

**Exhibit 31.1**

**CERTIFICATION PURSUANT TO**
**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**
**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Robert Alexander, certify that:

1. I have reviewed this Annual Report on Form 10-K of Allakos Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2019

By: /s/ Robert Alexander

**Robert Alexander**
**President and Chief Executive Officer**
**(Principal Executive Officer)**

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO**
**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**
**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Adam Tomasi, certify that:

1. I have reviewed this Annual Report on Form 10-K of Allakos Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2019

By: /s/ Adam Tomasi

**Adam Tomasi**
**Chief Operating Officer, Chief Financial Officer and Secretary**
**(Principal Financial and Accounting Officer)**

**Exhibit 32.1**

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Allakos Inc. (the "Company") on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 14, 2019

By: /s/ Robert Alexander

**Robert Alexander**
**President and Chief Executive Officer**
**(Principal Executive Officer)**

**Exhibit 32.2**

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO**
**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Allakos Inc. (the "Company") on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 14, 2019

By: /s/ Adam Tomasi

**Adam Tomasi**
**Chief Operating Officer, Chief Financial Officer and Secretary**
**(Principal Financial and Accounting Officer)**