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 001-38542

Kezar Life Sciences, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**47-3366145**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4000 Shoreline Court, Suite 300	
South San Francisco, CA	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 822-5600

Securities registered pursuant to Section 12(b) of the Act: Common stock, par value $0.001 per share; Common stock traded on the Nasdaq stock 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 aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2018, was approximately $267 million.

The number of shares of Registrant's Common Stock outstanding as of March 22, 2019 was 19,118,421.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement, or the Proxy Statement, for the 2019 Annual Meeting of Stockholders of the registrant are incorporated by reference into Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2018.

Table of Contents

In this report, unless otherwise stated or the context otherwise indicates, references to "Kezar Life Sciences," "the company," "we," "us," "our" and similar references refer to Kezar Life Sciences, Inc. and our wholly owned Australian subsidiary, Kezar Life Sciences Australia Pty Ltd. This report also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. In some cases, you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," or similar expressions, or the negative or plural of these words or expressions. These forward-looking statements include statements concerning the following:

- our plans to develop and commercialize our product candidates;
- the initiation, timing, progress and results of our current and future clinical trials and our research and development programs;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to successfully acquire or in-license additional product candidates on reasonable terms;
- our ability to maintain and establish collaborations or obtain additional funding;
- our ability to obtain regulatory approval of our current and future product candidates;
- our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates;
- our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources;
- the implementation of our business model and strategic plans for our business and product candidates;
- our intellectual property position and the duration of our patent rights;
- developments or disputes concerning our intellectual property or other proprietary rights;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to compete in the markets we serve;
- the impact of government laws and regulations;
- developments relating to our competitors and our industry; and
- the factors that may impact our financial results.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors" and elsewhere in this report. You should not rely upon forward-looking statements as predictions of future events.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we are under no duty to update or revise any of the forward-looking statements in this report, whether as a result of new information, future events or otherwise, after the date of this report.

PART I

Item 1. Business.

Overview

We are a clinical-stage biotechnology company, discovering and developing novel small molecule therapeutics to treat unmet needs in autoimmunity and cancer. Our lead product candidate, KZR-616, a first-in-class selective immunoproteasome inhibitor, has completed testing in healthy volunteers and is now enrolling a Phase 1b/2 clinical trial in lupus and lupus nephritis. We believe that the immunoproteasome is a validated target for the treatment of a wide variety of autoimmune diseases, given the compelling published activity seen with proteasome inhibitors administered to patients with severe autoimmune diseases. Our Phase 1a clinical trial results provide evidence that KZR-616 avoids the side effects caused by non-selective proteasome inhibitors, side effects that prevent them from being developed as a treatment in autoimmunity. Initial top-line results from the Phase 1b portion of our trial are expected in the second quarter of 2019, and we plan to initiate the Phase 2 portion of the trial in the second quarter of 2019 as well. In January 2019, we began enrolling healthy female patients in a Phase 1 trial to assess the safety, tolerability, pharmacokinetics and target inhibition of a simplified lyophilized formulation of KZR-616. We are also leveraging our protein secretion pathway research platform to discover and develop small molecule therapies targeting oncology indications and remain on-track to nominating the first clinical candidate in 2019.

We acquired exclusive worldwide rights to KZR-616 and an accompanying library of similar molecules pursuant to a license agreement with Onyx Therapeutics, Inc., or Onyx, a wholly owned subsidiary of Amgen, Inc., or Amgen, in June 2015. Patent coverage for KZR-616 extends to at least 2034. We intend to develop KZR-616 to address underserved autoimmune diseases, including lupus nephritis (LN), dermatomyositis (DM), and polymyositis (PM), where we have planned initial Phase 2 clinical trials, as well as other autoimmune indications. Our first Phase 2 clinical trial is intended to evaluate KZR-616 for the treatment of LN, which currently has no FDA or EMA-approved drugs.

Our Pipeline

The following table sets forth the status and initial focus of our lead product candidate:

Program	Therapeutic Indication	Development Stage & Anticipated Milestones				
		Discovery	Preclinical	Phase 1	Phase 2	Anticipated Milestones
KZR-616	Lupus Nephritis (LN)			Phase 1 in SLE patients		Phase 1b top-line data in Q2 2019; Phase 2 initiation in Q2 2019
	Dermatomyositis					Initiate Phase 2 in 2H 2019
	Polymyositis					Initiate Phase 2 in 2H 2019
	Orphan / autoimmune unmet need					Potential to initiate Clinical Program in 2H 2019
	Orphan / autoimmune unmet need					Potential to initiate Clinical Program in 2H 2019
Protein Secretion Program	Oncology					Clinical candidate nomination in 2H 2019
	Oncology					Discovery Efforts Ongoing
	Autoimmune unmet need					Discovery Efforts Ongoing

Our Strategy

Our strategy is to focus on the discovery, development and commercialization of novel small molecule therapeutics to address unmet medical needs. Key elements of our strategy are to:

- ***Rapidly advance KZR-616 in multiple autoimmune indications, including orphan diseases and other areas of unmet needs.*** We believe that KZR-616 has the potential to treat a wide range of autoimmune diseases. We are currently enrolling a Phase 1b/2 clinical trial in patients with lupus and lupus nephritis and plan to initiate trials in up to four additional autoimmune indications in 2019. Assuming positive results from these trials, we intend to explore registration-enabling trials in each indication. We believe we could be eligible for Breakthrough Therapy designation, Fast Track designation or orphan drug designation, which, if granted by the U.S. Food and Drug Administration, or FDA, may accelerate clinical development and regulatory review.
- ***Identify small molecule disruptors of the protein secretion pathway and advance them into IND-enabling studies.*** We believe we are the only company exploring the therapeutic potential of modulating the protein secretion pathway and the Sec61 translocon. We intend to leverage this platform to identify product candidates for the treatment of diseases with significant clinical need, initially in oncology and immuno-oncology.
- ***Develop next-generation immunoproteasome inhibitors.*** Over time, we intend to develop new chemistries with differentiated properties, alternate drug delivery methods, such as oral versus subcutaneous, or improved therapeutic windows.
- ***Leverage our technical and business expertise to expand our pipeline of small-molecule product candidates.*** Our management team, board of directors and clinical and scientific advisors have many years of institutional experience. As such, we intend to leverage the collective talent within our organization and network of advisors to guide our development plans and pipeline expansion, including acquiring or in-licensing small molecule compounds.
- ***Maximize the value of our programs by maintaining flexibility to commercialize our product candidates independently or through collaborative partnerships.*** We currently have exclusive global development and commercialization rights for our product candidates for all indications that we may pursue. While we may develop these products independently, we may also enter into strategic relationships with biotechnology or pharmaceutical companies to advance our product candidates.

Unmet Needs in Autoimmunity and the Opportunity for KZR-616

Approximately 50 million people in the United States suffer from more than 100 diagnosed autoimmune diseases according to the American Autoimmune Related Diseases Association, Inc. Large indications such as rheumatoid arthritis, inflammatory bowel disease and multiple sclerosis are well known, each afflicting millions of people, while many others are rare or orphan indications with prevalence rates in the United States of under 200,000. Across this spectrum, in indications large and small, there remain significant unmet medical needs and indications with no approved drugs beyond broadly prescribed steroids and similar immunosuppressive regimens.

Prevalence estimates of systemic lupus erythematosus, also known as lupus or SLE, and lupus nephritis in the United States vary, but recent industry estimates suggest over 460,000 and 100,000 patients, respectively. The presence of nephritis dramatically increases mortality risk in lupus patients, and there are currently no FDA-approved therapies for lupus nephritis. Among our other lead indications, dermatomyositis and polymyositis are serious disorders involving muscle inflammation and weakness with no FDA-approved therapies. According to the Myositis Association, an estimated 70,000 people in the United States have these disorders.

We closely track the multiple autoimmune diseases where Velcade® (bortezomib), a nonselective proteasome inhibitor, has demonstrated positive clinical activity, including lupus, lupus nephritis, idiopathic thrombocytopenic purpura, primary Sjögren's syndrome, rheumatoid arthritis, autoimmune hemolytic anemia and graft-versus-host disease. Although no randomized clinical trials have validated the therapeutic potential of Velcade in autoimmunity, these studies highlight the broad therapeutic potential of proteasome inhibition in general and immunoproteasome inhibition in particular for the treatment of autoimmune diseases.

Following is a partial list of indications where we may pursue development in the future. In all of the indications below, there is evidence supporting immunoproteasome inhibition as a therapeutic modality.

Indication	Clinical Data with VELCADE	Preclinical Data with Kezar Compounds (ONX 0914/KZR-616)
Lupus Nephritis (LN) and SLE	✓	✓
Graft vs Host Disease (GVHD)	✓	✓
Myasthenia Gravis (MG)	✓	✓
Rheumatoid Arthritis (RA)	✓	✓
Immune Thrombocytopenia (ITP)	✓	
Autoimmune Hemolytic Anemia (AHA)	✓	
IgA nephropathy (IgAN)	✓	
IgG4 related disease	✓	
Neuromyelitis Optica (NMO)	✓	
Pemphigoid	✓	
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	✓	
Anti-NMDA Encephalitis	✓	
ANCA-associated Vasculitis (AAV)	✓	
Multiple Sclerosis (MS)		✓
Crohn's Disease (CD)		✓

Autoimmune Disease

Autoimmune disease, or autoimmunity, is an immune response directed against the body's own healthy cells and tissues. Autoimmunity can be caused genetically, by infection, or can arise spontaneously, and the prevalence of these diseases is more prominent in females. Autoimmune disease usually involves an autoreactive response by both T-cells and B-cells, also known as lymphocytes, which attack the body's cells and tissues. In a healthy individual, as the immune system develops during childhood, autoreactive lymphocytes are eliminated or suppressed by various mechanisms. When any of these mechanisms fail, autoimmunity can arise. The presence of autoantibodies, a product of self-reactive B-cells, which react with the proteins, DNA, and lipids in healthy cells, is a hallmark of these diseases. Many autoimmune diseases are characterized by disease flares, in which symptoms worsen, followed by a period of remission, in which symptoms improve.

Many autoimmune diseases are not due to the direct effects of autoantibodies but rather due to other mechanisms that cause immune dysfunction. These include activation of inflammatory T-cells and cytotoxic T-cells, which can cause inflammation and tissue damage, the generation of cytokines that are harmful to the surrounding tissue, or activation of macrophages, a kind of immune cell, which can also lead to cytokine release, as well as cellular damage from free radicals. Examples of autoimmune diseases that we initially intend to target include lupus, lupus nephritis and idiopathic inflammatory myopathies.

Lupus is a chronic inflammatory disease that can affect various parts of the body. Most patients present with hematologic, renal or central nervous system manifestations. Significant complications of lupus include damage to joints and kidneys, cardiovascular issues and hematologic abnormalities. Many lupus patients, including those taking immunosuppressive agents and corticosteroids, experience disease flares. Lupus is mild in some people and life threatening in others. Immunologic abnormalities, particularly the production of autoantibodies, are a prominent feature of the disease.

About half of patients with lupus go on to demonstrate symptoms of renal dysfunction called lupus nephritis during the course of their disease. Autoantibodies, including those reacting with components of the cell's nucleus, often form immune complexes that deposit in the kidney and interfere with its ability to filter urine, decreasing kidney function and increasing protein found in the urine, or proteinuria. Immune complex deposition in the kidney can also activate other arms of the inflammatory response, including the recruitment of proinflammatory immune cells such as macrophages and T-cells, which further exacerbate kidney damage by secreting inflammatory cytokines, including TNF-α and IL-6. Lupus nephritis patients have a significantly increased risk of kidney failure and death relative to lupus patients who do not have lupus nephritis.

Idiopathic inflammatory myopathies are a group of autoimmune diseases in which inflammation occurs in muscles and often in other parts of the body, predominantly the skin. These conditions, which lead to a rash and loss of muscle function, include dermatomyositis, polymyositis, juvenile dermatomyositis, juvenile polymyositis and autoimmune necrotizing myopathy. The cause of idiopathic inflammatory myopathies remains undetermined although most patients present with disease specific autoantibodies.

In most autoimmune diseases, initial therapy consists of long-term treatment with a combination of immunosuppressive agents, such as methotrexate or CellCept® (mycophenolate mofetil), and daily administration of high-dose corticosteroids. This treatment regimen results in high rates of infection, increased risk of malignancy and a wide variety of side effects arising from prolonged steroid use and, in diseases such as lupus nephritis, does not induce high rates of clinically meaningful responses. These treatments can be associated with anemia and other serious side effects. Targeted agents, such as TNF-α antagonists, are used in some autoimmune diseases, such as rheumatoid arthritis, after immunosuppressive agents have failed. Generally, these agents are ineffective in a wide range of autoimmune diseases, including lupus nephritis and idiopathic inflammatory myopathies. However, even if these agents are initially effective, over time patients often experience loss of response.

Protein Degradation and Selective Inhibition of the Immunoproteasome

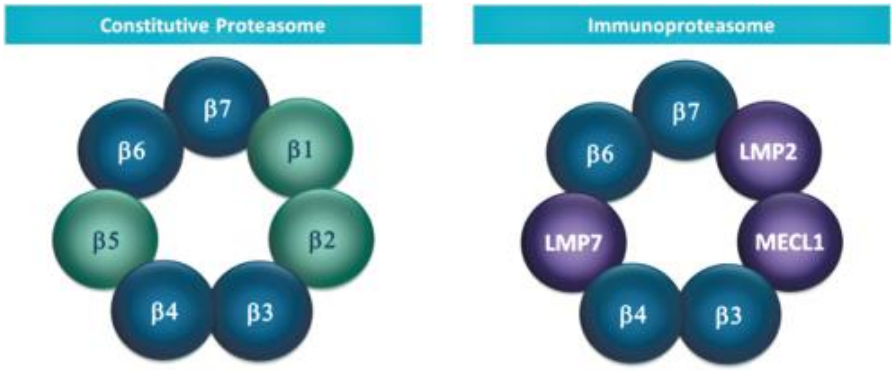
Selective inhibition of the immunoproteasome has the potential to reduce inflammation by targeting dysfunctional immune cells involved in autoimmunity, such as T-cells and B-cells, without causing widespread immunosuppression.

The Constitutive Proteasome and the Immunoproteasome

Found in all cells of the body, proteasomes regulate intracellular protein degradation and are essential for many cellular processes such as cell division, cell differentiation and cytokine production. There are two main forms of the proteasome: the constitutive proteasome and the immunoproteasome. In most tissues of the body, the constitutive proteasome is the predominant form. In cells of the immune system, the immunoproteasome is the predominant form.

While both forms of the proteasome mediate protein degradation, the two forms of the proteasome accomplish this utilizing different active sites, which are depicted in the figure below. In the immunoproteasome, three active sites, LMP7, LMP2 and MECL1, replace the constitutive proteasome subunits β5, β1 and β2. These active sites are responsible for cleaving and degrading proteins.

Depiction of a Portion of the Constitutive Proteasome and the Immunoproteasome



Depiction of the core particle (also known as the 20S particle) of the constitutive proteasome and immunoproteasome. Active sites for protein degradation are highlighted.

Safety and Efficacy of Approved Proteasome Inhibitors

The three proteasome inhibitors approved for the treatment of multiple myeloma, Velcade, Kyprolis and Ninlaro, are potent "dual inhibitors" of both the immunoproteasome and the constitutive proteasome, primarily the LMP7 and β5 subunits, respectively. This dual-targeting profile is necessary to make them effective treatments for multiple myeloma. However, dual proteasome inhibition is associated with hematologic issues such as thrombocytopenia, neutropenia and anemia, as well as constitutional toxicities such as fatigue and myalgia. In addition, Velcade and Ninlaro are associated with risk of peripheral neuropathy, likely due to the off-target activity of these drugs against proteins found in peripheral neurons.

Velcade has demonstrated clinical activity in several autoimmune diseases, including lupus, lupus nephritis, idiopathic thrombocytopenia purpura, autoimmune hemolytic anemia, primary Sjögren's syndrome and graft-versus-host disease. In preclinical models, proteasome inhibition blocked production of most inflammatory cytokines, including many of those targeted by current biologic drugs. However, long-term, chronic administration of Velcade in the setting of autoimmune diseases is not considered feasible due to its side effect profile, in particular hematologic toxicities and risk of peripheral neuropathy. As a result, this promising drug target has remained untapped for use in the treatment autoimmune diseases.

KZR-616

Overview

We believe we are the only company with a selective immunoproteasome inhibitor that has been nominated as a clinical candidate or is in clinical trials. In addition, we believe that KZR-616, if successfully developed and approved, may have the ability to become the standard of care across a broad range of autoimmune diseases based on the following expected key attributes:

- broad immunomodulatory activity that may allow it to outperform approved therapies and to work in indications where other drugs have failed;
- lack of significant immunosuppression, a key drawback to other approved therapies in autoimmunity; and
- avoidance of systemic toxicities associated with dual proteasome inhibitors and the peripheral neuropathy associated with Velcade and Ninlaro.

The first selective immunoproteasome inhibitors were discovered by our co-founder and Chief Scientific Officer and his colleagues at Proteolix, Inc., or Proteolix, in 2005. Proteolix was acquired by Onyx in 2009, and Onyx was acquired by Amgen in 2013. In tests of these compounds in multiple in vitro and in vivo models, it was ascertained that these molecules did not demonstrate cytotoxic activity or potential as anti-cancer agents. However, it was observed that these inhibitors had profound immunomodulatory effects across myriad immune cell types. In over 15 peer-reviewed publications, our selective inhibitors of the immunoproteasome and related compounds have demonstrated strong therapeutic potential in animal models of multiple autoimmune diseases.

Broad Immunomodulatory Activity

In preclinical models of inflammation, selective inhibitors of the immunoproteasome block cytokine production and result in therapeutic activity equivalent to or better than Velcade or Kyprolis. In mouse models of lupus, our first widely studied selective inhibitor of the immunoproteasome, ONX 0914, showed equivalent efficacy and better tolerability than Velcade. In addition, KZR-616 has been shown to block disease progression and prevent renal damage in animal models of lupus nephritis in a manner that is significantly better than current standard of care therapy, CellCept. This body of research strongly suggests that the therapeutic benefit of Velcade in patients with autoimmune diseases such as lupus is due to targeting of the immunoproteasome. In one of those peer-reviewed publications, ONX 0914 resulted in a deeper anti-inflammatory response relative to Enbrel® (etanercept), a TNF-α antagonist.

Lack of Immunosuppression

Standard therapies for most autoimmune diseases involve long-term use of immunosuppressive agents and daily administration of corticosteroids, resulting in high rates of infection, increased risk of malignancy and other side effects. In the setting of multiple myeloma, the dual proteasome inhibitors Velcade and Kyprolis are not associated with a high risk of immunosuppression. In animal models, selective immunoproteasome inhibitors showed a lack of immunosuppression, and KZR-616 was shown to mediate an anti-inflammatory response in models of autoimmunity without the addition of steroids.

Targeted agents, such as TNF-α antagonists, lack sufficient therapeutic activity in diseases such as lupus and lupus nephritis due in part to broad immune dysfunction in these diseases. Selective immunoproteasome inhibitors, including KZR-616, have shown direct immunomodulatory activity against the vast majority of cytokines and activated immune cells known as effector cells involved in autoimmune diseases. Therefore, we believe KZR-616 represents a novel therapy with the potential to reduce steroid burden and to provide clinical benefit in patients with autoimmune diseases that cannot be treated by current targeted agents.

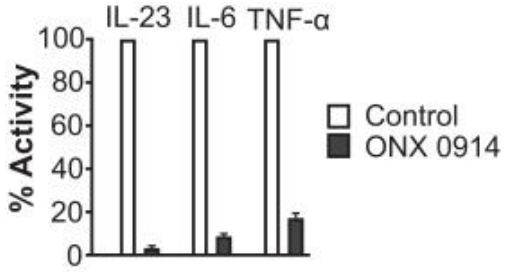
Avoids Systemic Toxicity or Neurotoxicity

In animal models of toxicology, KZR-616 was able to induce potent inhibition of the immunoproteasome without inducing systemic toxicities seen in animals treated with Kyprolis and Velcade. Specifically, KZR-616 did not induce hematologic abnormalities or indications of cardiovascular, hepatic or renal toxicity in animals, findings that were commonly noted in animals receiving the dual-proteasome inhibitors. In addition, KZR-616, a peptide epoxyketone-based inhibitor of the immunoproteasome, has shown no off-target effects or signs of neurotoxicity in preclinical studies. This finding is in contrast to Velcade and Ninlaro, which are boronic acid-based proteasome inhibitors that induce potent inhibition of several off-targets, including an enzyme required for the normal function of neurons.

Preclinical Data with Kezar Compounds and Clinical Data with Velcade Support KZR-616 Development

Most autoimmune diseases arise in part due to overexpression of secreted proteins called cytokines. Several of these cytokines, such as TNF-α, have been successfully targeted with biologic agents. When applied to human immune cells such as monocytes, selective immunoproteasome inhibitors, like KZR-616 and ONX 0914, blocked the release of inflammatory cytokines following cell stimulation. The cytokines whose secretion is inhibited include IL-23, IL-6, and TNF-α, which are variously targeted by approved monoclonal antibody therapeutics such as Actemra® (tocilizumab), Enbrel, Humira® (adalimumab) and Stelara® (ustekinumab).

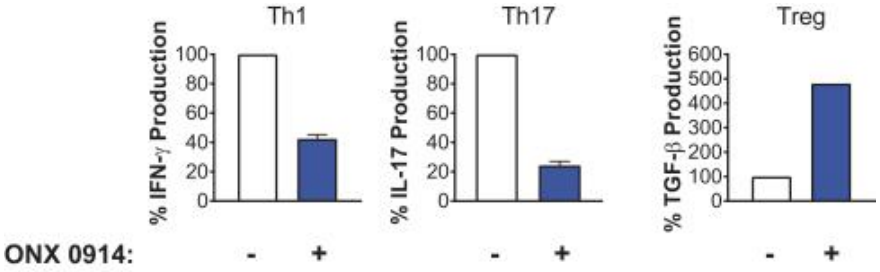
Administration of ONX 0914 Blocked the Release of Cytokines



Human peripheral blood mononuclear cells, which are white blood cells, from healthy donors were stimulated to produce cytokines with the agent lipopolysaccharide.

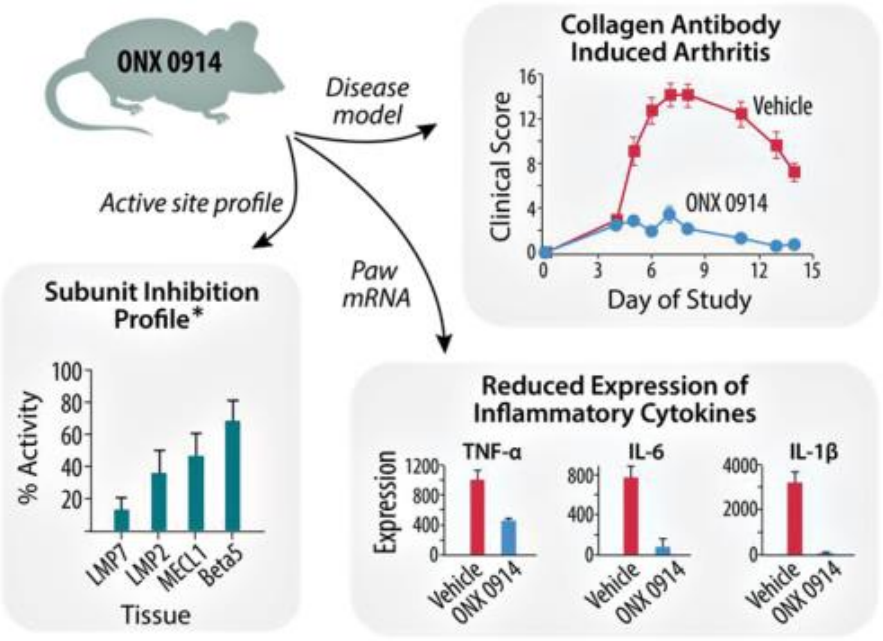
Activated T-cells can induce inflammation when they differentiate into immune effector cells, such as Th1 and Th17, and express cytokines, such as IFN-γ and IL-17. Cosentyx® (secukinumab), which targets IL-17, is approved for certain autoimmune diseases. Inhibition of the immunoproteasome in activated T-cells causes a reduction in Th1 and Th17 activity. Conversely, several autoimmune diseases are thought to be mediated in part by a reduction in the number of regulatory T-cells, or Tregs, which can reduce inflammation in part via secretion of the cytokine TGF-β. Inhibition of the immunoproteasome increases the activity of Treg cells in part via increased TGF-β production. The graph below shows the results from an experiment measuring the effect of immunoproteasome inhibition on human Th1, Th17 and Treg cells following a one hour exposure to ONX 0914 followed by restimulation to measure cytokine release.

Immunoproteasome Inhibitor ONX 0914 Blocked Th1 and Th17 Inflammatory Cells and Increased Regulatory T-Cell Activity



KZR-616 and ONX 0914 have been observed to be therapeutically active in multiple animal models of autoimmunity, including lupus, lupus nephritis, rheumatoid arthritis, inflammatory bowel disease, multiple sclerosis and Type 1 diabetes. As shown in the figure below, in a mouse model of rheumatoid arthritis, administration of a single dose of ONX 0914, which induced potent and selective inhibition of the immunoproteasome, was sufficient to induce complete disease remission and inhibit the expression of several inflammatory cytokines in the animals. Inhibition of all three immunoproteasome active sites (LMP7, LMP2 and MECL1) was induced by ONX 0914 with minimal impact on the β5 subunit of the constitutive proteasome. The mice were followed for 14 days for signs of inflammation in their joints, and expression of three inflammatory cytokines was measured on Day 7 of the study. In a peer-reviewed publication, ONX 0914 resulted in a deeper anti-inflammatory response relative to Enbrel.

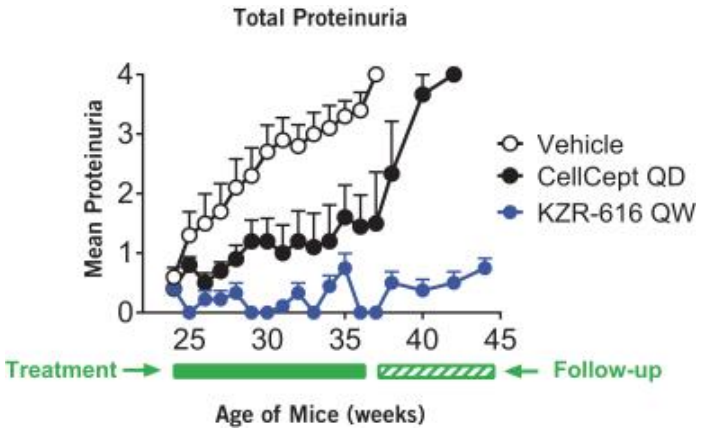
A Single Dose of ONX 0914 Selectively Inhibited Immunoproteasome Active Sites and Reduced Inflammation and Cytokine Expression in a Rheumatoid Arthritis Model



*same assay as used in Phase 1a clinical trial of KZR-616

In a mouse model of lupus nephritis, KZR-616 was compared to the standard of care, CellCept, for 12 weeks of therapy and 8 weeks of follow-up after the last dose. Compared to CellCept, KZR-616 induced a greater improvement in renal response as measured by reduced proteinuria. CellCept was active in this model, but, notably, renal disease progressed as soon as treatment stopped. In the mice treated with once weekly administration of KZR-616, a prolonged prevention of renal disease was noted out to eight weeks after the last dose, suggesting long-lasting immunomodulation. The effects of KZR-616 were not limited to a reduction in proteinuria; KZR-616 therapy also reduced kidney damage (measured histologically), decreased the number of activated B-cells and autoantibody producing B-cells and reduced levels of autoantibodies.

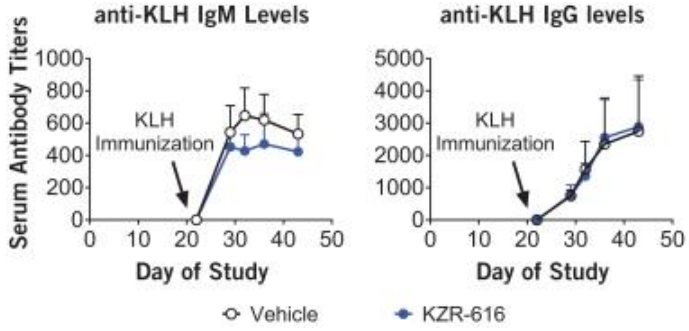
KZR-616 Successfully Treated Renal Disease in a Lupus Nephritis Mouse Model and Outperformed a Standard of Care Therapy



In mice with active lupus nephritis, KZR-616 or CellCept was given to animals for 12 weeks. QD means once per day and QW means once per week. Proteinuria was measured weekly or biweekly for 20 weeks.

Immunosuppression, the inability of the body's immune system to generate antibodies to vaccines or to fight off infection, is a common side effect of many drugs approved for or in development in autoimmunity. To assess the risk of immunosuppression due to treatment with our selective immunoproteasome inhibitors, our scientists and their academic collaborators performed several studies in animal models. Mice receiving daily administration of ONX 0914 experienced no loss in the ability to fight off viral infections. Nonhuman primates receiving weekly doses of KZR-616 raised normal antibody levels following immunization with the antigen KLH.

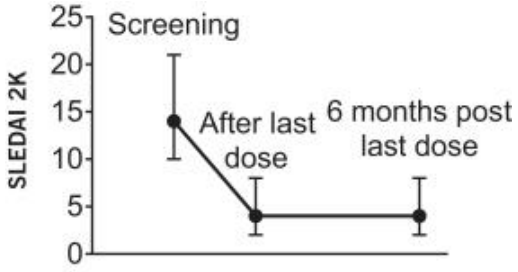
Nonhuman Primates Receiving KZR-616 Demonstrated Normal Antibody Responses



Nonhuman primates were given KZR-616 once per week and were immunized on Day 21 with KLH. Levels of antibodies raised against KLH were measured out to 21 days after immunization.

In parallel to the development of immunoproteasome inhibitors at Proteolix and Onyx, independent clinical researchers were exploring the application of the dual proteasome inhibitor Velcade in patients with persistent and treatment refractory autoimmune diseases. In one investigation, Velcade was administered for up to three months in patients with lupus who had previously been treated with standard of care but were still experiencing severe symptoms. Clinical responses were seen in all patients and improvements in disease symptoms were seen as early as 21 days from the start of treatment. In the subset of lupus patients with lupus nephritis, Velcade induced meaningful reduction in proteinuria with a median decrease of over 60% during the treatment period.

Velcade Reduced Lupus Disease Severity

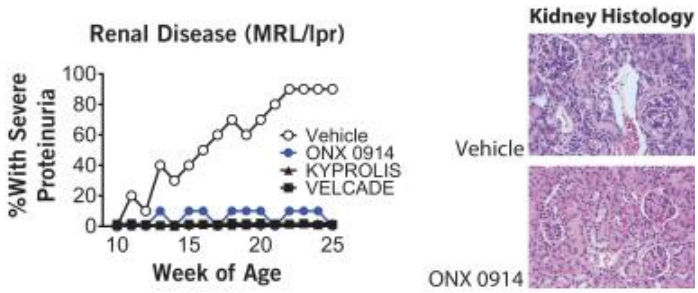


16 lupus patients were treated with Velcade for up to 4 treatment cycles. Disease severity as measured by the systemic lupus erythematous disease activity index, or SLEDAI 2K scale, was monitored prior to the first dose of Velcade, after the last dose of Velcade and 6 months after the last dose of Velcade. Median data from all patients are shown. Adapted from Alexander et al. 2015

Despite this clinical activity in lupus, Velcade is not suitable for long-term administration in any chronic inflammatory or autoimmune disease. This is due to Velcade's associated hematologic adverse events such as thrombocytopenia, anemia and neutropenia and induces peripheral neuropathy that can become permanent if dosing is continued for an extended period of time.

As shown in the figure below, our selective immunoproteasome inhibitor ONX 0914 was compared to dual targeting proteasome inhibitors Velcade and Kyprolis in mouse models of lupus. ONX 0914 was found to replicate the therapeutic activity of the dual proteasome inhibitors in these models, which strongly suggests that the clinical activity of Velcade and Kyprolis in patients with lupus is due to immunoproteasome inhibition. In fact, selective immunoproteasome inhibition resulted in equivalent efficacy and better tolerability in animal models to that of dual proteasome inhibitors. Also, selective immunoproteasome inhibition induced similar reductions in autoantibodies, cytokine reduction and autoimmune cell reduction to those demonstrated by dual-proteasome inhibitors.

Immunoproteasome Inhibition Was as Effective as Velcade and Kyprolis in Mouse Models of Lupus and Lupus Nephritis



In mice with active nephritis, ONX 0914, Velcade or Kyprolis was given to animals for 12 weeks. Renal disease was measured by monitoring proteinuria and at the end of study kidneys were analyzed by histology for disease-related changes.

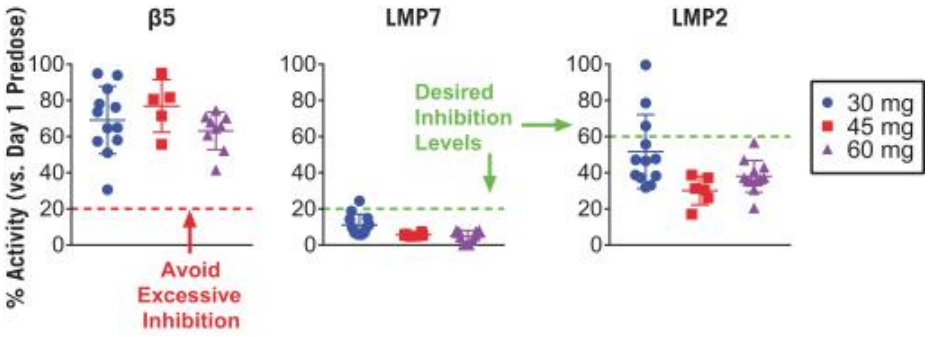
Our Phase 1a Clinical Data with KZR-616

In 2017, we completed a Phase 1a clinical trial in Australia to assess the safety, tolerability, pharmacokinetics, or PK, pharmacodynamics, or PD, and immunomodulatory activity of KZR-616 in 82 healthy volunteers. In this trial, KZR-616 or a placebo was administered as a single dose or repeat-weekly subcutaneous administration over four weeks. Results from the trial, including the data and figures below, were presented at the 2017 American College of Rheumatology Annual Meeting.

Administration of KZR-616 to healthy volunteers resulted in a dose-dependent increase in exposure and inhibition of immunoproteasome activity. Selective inhibition of the immunoproteasome over the constitutive proteasome was demonstrated using multiple PD assays. Cytokine levels in ex vivo stimulation assays demonstrated an anti-cytokine effect of KZR-616 treatment consistent with preclinical models. Single and weekly administration at a dose that resulted in potent inhibition of the immunoproteasome were well tolerated and did not result in any of the hematologic adverse events that are often seen with Velcade and Kyprolis. In addition, there were no changes in liver or kidney function, ECG abnormalities, prolonged constitutional adverse events, or signs of immunosuppression with weekly administration of KZR-616.

In our Phase 1a healthy volunteer study, we observed that PK and PD were consistent across subjects and with repeat dosing. The graphs below show the proteasome subunit inhibition profiles in healthy volunteers receiving a single dose of either 30, 45, or 60 mg of KZR-616. At a 30 mg dose, 75% of the subjects (9 of 12) achieved the desired inhibition of the immunoproteasome subunits LMP7 and LMP2 and all subjects avoided 80% inhibition of the ß5 subunit of the constitutive proteasome. In contrast, Kyprolis induces greater than 80% inhibition of both LMP7 and ß5 at its labeled dose. All subjects receiving a dose of 45 or 60 mg achieved the desired inhibition of both LMP7 and LMP2 and also avoided excessive inhibition of the ß5 subunit.

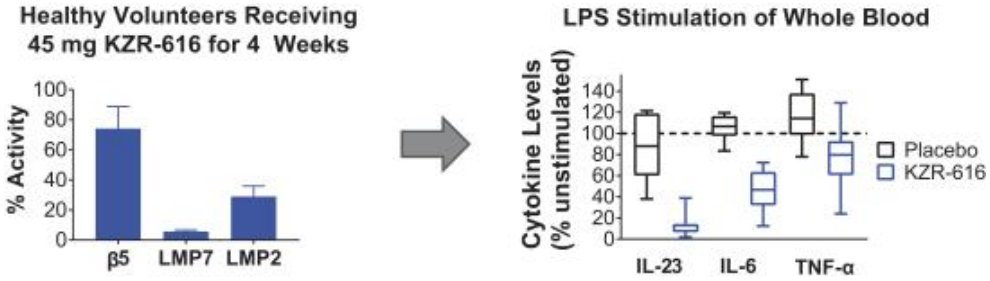
KZR-616 Inhibited Both LMP7 and LMP2 While Avoiding Excessive Inhibition of ß5, thereby Demonstrating Selective Immunoproteasome Inhibition



In Phase 1a subjects receiving subcutaneous administration of KZR-616, the most common adverse events, or AEs, were injection site reactions that were generally mild and transient and did not appear to increase in severity or frequency with repeat dosing. In addition, at the 60 mg dose level, two separate cohorts of six subjects each received a single dose of KZR-616. In the second cohort, 4 of 6 subjects receiving drug experienced AEs with a preferred term of adverse drug reactions, namely hypotension, sinus tachycardia, nausea, vomiting and rigors and chills. Two of these subjects' reactions were classified as Grade 2 and were recorded as serious adverse events, or SAEs. These systemic drug reactions appear similar to reactions reported upon initial infusion of carfilzomib. These findings were not seen with repeat dosing at 45 mg, and we conducted no repeat dosing at the 60 mg dose level.

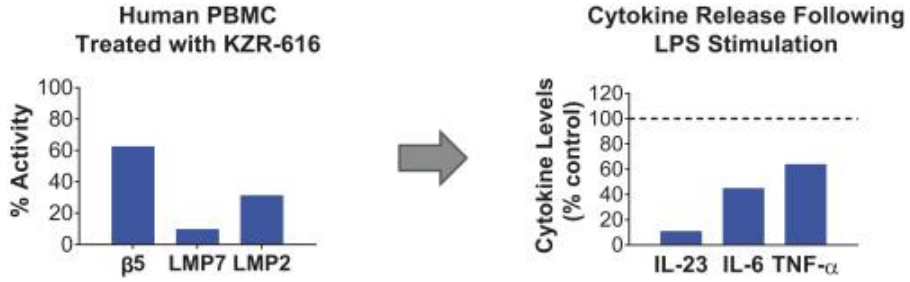
In order to determine whether KZR-616 was having a biologic effect in healthy volunteers, blood samples were taken before and after dosing and stimulated ex vivo to induce release of cytokines from white blood cells in the blood samples. We observed that after repeat dose administration of KZR-616 at a dose of 45 mg, there was significantly reduced release of cytokines compared to subjects receiving placebo. The following figure shows the profile of proteasome subunit inhibition in the healthy volunteers receiving 45 mg of KZR-616 and the resulting reduction in cytokine release following stimulation with lipopolysaccharide, or LPS.

Profile of Proteasome Subunit Inhibition in Healthy Volunteers Receiving KZR-616 and the Resulting Inhibition of Cytokine Release Following Stimulation



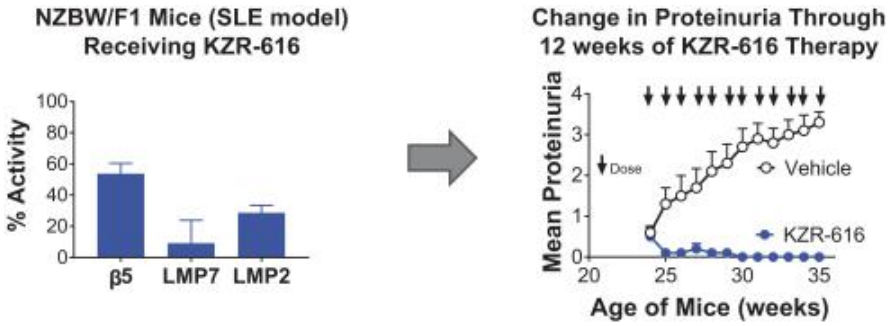
This profile of proteasome subunit inhibition is very similar to that observed when we treat white blood cells in vitro and stimulate them to release the same cytokines. As seen in the figure below, we demonstrated in vitro with human peripheral blood mononuclear cells, or PBMC, that a similar immunoproteasome subunit inhibition profile resulted in a comparable biologic response, namely inhibition of cytokine release.

Profile of Proteasome Subunit Inhibition in PBMC Exposed In Vitro to KZR-616 and the Resulting Inhibition of Cytokine Release Following Stimulation



Similarly, we have also shown that a dose of KZR-616 in mice can induce a similar immunoproteasome inhibition profile to that seen in human cells treated in vitro and in healthy volunteers receiving a dose of 45 mg. When KZR-616 was administered weekly for 12 weeks in a mouse model of lupus, mice saw a complete resolution of their nephritis, as measured by the absence of proteinuria.

Profile of Proteasome Subunit Inhibition in Mice Receiving KZR-616 and the Resulting Remission of Proteinuria in a Mouse Model of Lupus Nephritis



These data sets demonstrate a consistency of immunoproteasome inhibition profiles and anti-inflammatory activity across both preclinical and clinical settings. We believe these data, together with our other preclinical data demonstrating inhibition of multiple inflammatory cytokines and efficacy in animal models of autoimmune diseases, demonstrate the potential for KZR-616 to be a promising new agent for the treatment of several autoimmune disorders.

Ongoing and Planned Clinical Development

Following the completion of our Phase 1a clinical trial in healthy volunteers, we filed an investigational new drug application, or IND, with the Division of Pulmonary and Rheumatology Products at the FDA.

The IND is currently open with the FDA, and in March 2018, we began enrollment of patients in KZR-616-002, a multi-center Phase 1b/2 clinical trial in patients with lupus and lupus nephritis. The Phase 1b portion includes open-label dose escalation in patients with active lupus (with and without lupus nephritis) who have failed to respond to at least one standard therapeutic regimen, such as Benlysta® (belimumab) or an immunosuppressive agent such as CellCept® (mycophenolate mofetil). All patients must have a SLEDAI (Systemic Lupus Erythematosus Disease Activity Index) score of 4 or higher and must have measurable levels of autoantibodies. In this portion of the trial, we plan to enroll up to four cohorts of four to six patients each at dose levels of 45, 60, 75 and 90 mg. Each patient will receive up to 13 weekly subcutaneous administrations of KZR-616, and new cohorts will initiate enrollment after the previous cohort clears a four-week safety review. Enrollment is ongoing. The primary endpoints of both portions of the trial are safety and tolerability. Secondary and exploratory endpoints include PK, PD and biomarker assessments and measures of efficacy. We intend to use the data generated from the Phase 1b portion to select the doses for the Phase 2 portion of the trial. Initial top-line results from the Phase 1b portion of the trial are expected in the second quarter of 2019.

The Phase 1b portion of KZR-616-002 allows for two additional expansion cohorts in which we may evaluate KZR-616 in different subsets of patients or with different dosing regimens. If we choose to pursue these cohorts, we expect to initiate enrollment of these cohorts in 2019.

Once the dose levels of 45 and 60 mg have cleared safety review in the Phase 1b portion of the trial, we intend to commence the Phase 2 portion and remain on track to do so in the second quarter of 2019. The Phase 2 portion is a randomized placebo-controlled, double-blind trial to evaluate the safety and efficacy of KZR-616 in patients with active proliferative lupus nephritis. Inclusion criteria include patients with active proliferative lupus nephritis (Class III or IV ±V) who are undergoing induction therapy with CellCept and prednisone and have been treated for one to three months with this regimen. Patients will be randomized equally to one of three arms, KZR-616 at 1 of 2 doses or placebo. All patients will remain on their background induction therapy during the 13-week treatment period.

In January 2019, we began enrolling healthy female subjects in a Phase 1, randomized, double-blind, placebo controlled, single and multiple ascending dose study to assess the safety, tolerability, PK, and target inhibition of a

simplified lyophilized formulation of KZR-616. The trial is being conducted in Australia and will enroll up to 72 healthy female subjects. A simplified lyophilized formulation of KZR-616 has the potential to improve the ease of drug administration, transportation, storage and ease of administration. Additionally, data from this trial may be used to support development and potential regulatory approval.

We plan to initiate Phase 2 trials in up to four additional indications in 2019 to assess the safety, pharmacology and clinical activity of KZR-616 in autoimmune diseases. The first of these will likely be a randomized Phase 2 clinical trial in patients with dermatomyositis and polymyositis. We expect to select additional indications based on assessment of clinical and regulatory feasibility and scientific evidence demonstrating a potential therapeutic benefit for KZR-616. We expect these indications to be autoimmune diseases that are orphan indications or other areas of high unmet medical need.

If our early trials demonstrate meaningful clinical activity, we intend to apply for various regulatory designations, possibly including Breakthrough Therapy designation, Fast Track designation or orphan drug designation. Receiving any of these designations could result in priority review from the FDA upon submission of a marketing application. In addition, some orphan indications we are considering may require smaller safety databases and therefore smaller numbers of patients for approval. Finally, by targeting indications with high unmet medical need, KZR-616 may face less competition and, if approved, enjoy a better chance of rapid uptake by physicians and patients eager to find effective treatments.

Protein Secretion and the Sec61 Translocon

We are conducting research and discovery efforts targeting protein secretion pathways as potential therapies for oncology and immuno-oncology. In mammalian cells, the secretion of proteins such as cytokines and the expression of cell surface transmembrane proteins such as cytokine receptors involve a process called cotranslational translocation. This process entails the insertion of nascent polypeptides, which are proteins, into the endoplasmic reticulum, or ER, of the cell. For most proteins, this insertion into the ER occurs via the Sec61 translocon, a highly conserved multi-subunit protein complex found in the membrane of the ER of all cells. Inhibition of the Sec61 translocon with small molecules blocks the secretion of some or all proteins, which can result in several physiologic outcomes, including altered cellular function, inhibition of cytokine release and/or cell death.

We are currently conducting multiple drug discovery campaigns within our protein secretion research program. Our two main approaches are to discover and develop small molecule therapeutics that target the interaction of the unique signal sequences of newly created proteins with the Sec61 translocon, which we refer to as specific protein secretion inhibitors or SPSIs, and to block protein secretion broadly with agents, referred to as cotransins. Some of our drug discovery campaigns within our protein secretion research program have reached the stage of animal testing, including animal models of cancer, with promising initial results.

Our scientists and co-founder Dr. Jack Taunton of UCSF, have developed a significant level of proprietary knowledge around Sec61 translocon biology, the pharmacology and toxicology of protein secretion inhibitors, and know-how for determination of optimal properties for drug candidates.

We believe this program is advancing well and will be showcased in two poster presentations at the upcoming American Association for Cancer Research (AACR) in Atlanta, GA on April 2, 2019. We remain on track to nominate a first clinical candidate in oncology this year.

License Agreement with Onyx

In June 2015, in connection with an issuance of 1,121,384 shares of our Series A convertible preferred stock to Onyx, we entered into a license agreement with Onyx, or the Onyx license agreement. Pursuant to the Onyx license agreement, Onyx granted us an exclusive license under certain patent rights, and a non-exclusive license to certain know-how, in each case controlled by Onyx and relating to our immunoproteasome program, to develop, manufacture or commercialize any pharmaceutical product containing certain types of compounds that are selective for the immunoproteasome for any and all uses other than those related to the diagnosis and/or treatment in humans

of cancerous or pre-cancerous diseases and/or conditions, including those related to hematological diseases and/or conditions that are not inflammatory diseases or disorders.

Under the Onyx license agreement, we are obligated to pay Onyx milestone payments of up to $172.5 million in the aggregate upon the achievement of certain development, regulatory and sales milestones. Commencing upon the first commercial sale of a licensed product, we must make royalty payments to Onyx on net sales of such licensed products based on tiered annual net sales thresholds at varying royalty rates ranging in the mid to high single digits, subject to certain customary reductions. We must pay such royalties on a product-by-product and country-by-country basis until the latest to occur of the expiration of all licensed patents that claim such product in such country, the loss of regulatory exclusivity for such product in such country and the tenth anniversary of the first commercial sale of such product in such country. The licensed product patent portfolio includes issued patents in the United States, Australia, Canada, China, Europe, Japan, Mexico, Singapore and South Korea with expiration dates ranging from 2027 to 2034, absent any patent extensions available. For more information on our intellectual property, see "Business — Intellectual Property." Upon the expiration of such royalty term in such country, our license to such product will become fully paid-up, irrevocable, and non-exclusive.

Under the Onyx license agreement, Onyx has a right of first negotiation to obtain a license, or a similar transfer of rights, to develop and/or commercialize any licensed product.

The Onyx license agreement will remain in effect until the expiration of last-to-expire royalty term for any licensed product in the territory. The license agreement may be terminated by us with prior notice, by either party in the event of a material breach by the other party that remains uncured for a certain number of days, such number depending on the type of breach, by either party for insolvency of the other party, or immediately by Onyx if we challenge any of the licensed patents.

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to build a commercial infrastructure to support sales of KZR-616 in the United States. We expect to manage sales, marketing and distribution through internal resources and third-party relationships. While we may commit significant financial and management resources to commercial activities, we will also consider collaborating with one or more pharmaceutical companies to enhance our commercial capabilities. Outside the United States, we plan to seek pharmaceutical partners for sales and marketing activities.

Manufacturing

Our internal manufacturing capabilities include production of small-scale quantities of active pharmaceutical ingredient, or API, for characterization and preclinical assessment of product candidates. We do not own or operate manufacturing facilities compliant with current good manufacturing practices, or cGMP, and we do not have plans to develop our own cGMP manufacturing operations in the foreseeable future.

We currently rely on third-party contract manufacturing organizations, or CMOs, for all of our required raw materials, API and finished product for our clinical trials and for most of our preclinical research. We also contract with additional third parties for the filling, labeling, packaging, storage and distribution of investigational drug products. We maintain agreements with our CMOs that include confidentiality and intellectual property provisions to protect our proprietary rights related to KZR-616. We obtain our supplies from these CMOs on a purchase order basis, and do not have long term supply agreements in place. We do not have arrangements in place for redundant supply; however, we believe we can identify and establish additional CMOs to provide API and finished drug product without significant disruption to our business or clinical development timelines.

Development and commercial quantities of any products that we develop will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval. If KZR-616 is approved by any regulatory agency, we intend to enter into agreements with a third-party contract manufacturer and one or more backup manufacturers for the commercial production of KZR-616.

Starting with the Phase 2 trial, KZR-616 will be a lyophilized product candidate, meaning it is freeze-dried and must be reconstituted with water prior to delivery to a patient. While lyophilized products are common in the drug industry, we intend that if approved and commercialized, KZR-616 will be self-administered by patients via a dual-chamber system. There are several technical challenges we will need to solve related to the use of a self-administered dual-chamber system, including whether KZR-616 is amenable to use in such a device and is sufficiently stable to meet regulatory requirements. In addition, we will need to enter into an additional agreement with a CMO to manufacture the self-administered dual-chamber system. We are aware of only one company that manufactures a self-administered dual-chamber system that has received FDA approval.

Competition

Drug development is highly competitive and subject to rapid and significant technological advancements. Our ability to compete will significantly depend upon our ability to complete necessary clinical trials and regulatory approval processes, and effectively market any drug that we may successfully develop. Our current and potential future competitors include pharmaceutical and biotechnology companies, academic institutions and government agencies. The primary competitive factors that will affect the commercial success of any product candidate for which we may receive marketing approval include efficacy, safety, tolerability, dosing convenience, price, coverage and reimbursement. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries.

Our current and potential future competitors may also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Accordingly, our competitors may be more successful than us in obtaining regulatory approval for therapies and in achieving widespread market acceptance of their drugs. It is also possible that the development of a cure or more effective treatment method for the disorders we are targeting by a competitor could render our current or future product candidates non-competitive or obsolete or reduce the demand for our product candidates before we can recover our development and commercialization expenses.

We are aware of two companies engaged in drug discovery and development of selective inhibitors of the immunoproteasome. Principia Biopharma, Inc. is currently engaged in pre-clinical research focused on the discovery of orally bioavailable and selective inhibitors of the immunoproteasome. Merck KgaA has recently disclosed an LMP7-selective inhibitor that has been nominated for clinical development in Multiple Myeloma. There has been no mention of clinical trials in autoimmune disorders.

Currently, lupus is treated with corticosteroids and immunosuppressive agents such as azathioprine. Current guidance for the treatment of proliferative lupus nephritis involves induction therapy with either CellCept or Cytoxan® (cyclophosphamide) and corticosteroids. In addition, Benlysta, an anti-BAFF monoclonal antibody from GlaxoSmithKline is approved by the FDA for the treatment of moderate to severe lupus but not lupus nephritis.

Other companies are developing agents to treat both lupus and lupus nephritis. In lupus, these agents include antibodies against the interferon alpha receptor, such as anifrolumab from AstraZeneca, and against IL-23/IL-12, such as Stelara from Janssen Biotech, Inc., and small molecule agents targeting JAK, such as baricitinib from Eli Lilly and Co., cereblon from Celgene, and BTK, such as evobrutinib, under evaluation by Merck KgaA.

In active, proliferative lupus nephritis, other companies are developing novel agents to add to the standard induction regimens and include Benlysta, anifrolumab and the investigational immunosuppressive agent, voclosporin, from Aurinia Pharmaceuticals, Inc.

Intellectual Property

Our intellectual property is critical to our business and we strive to protect it, including by obtaining and maintaining patent protection in the United States and internationally for our technology platform, product candidates, novel biological discoveries, new therapeutic approaches and potential indications, and other inventions that are important to our business. Our policy is to seek to protect our proprietary and intellectual property position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how that is not patentable, we rely on confidentiality agreements to protect our interests. We require our employees, consultants and advisors to enter into confidentiality agreements prohibiting the disclosure of confidential information and requiring disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

For our product candidates, generally we initially pursue patent protection covering compositions of matter and methods of use. Throughout the development of our product candidates, we seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through additional methods of use, process of making, and salt and polymorph related claims.

In total, our patent portfolio, including patents licensed from Onyx, comprises 11 different patent families, filed in various jurisdictions worldwide, including families directed to composition of matter for selective immunoproteasome inhibitors and protein secretion inhibitors. Four additional patent filings for new composition of matter subject matter were filed in the first quarter of 2019. Our patent portfolio includes issued patents in, among other jurisdictions, the United States, Australia, Canada, China, Europe, Japan, Mexico, Singapore and South Korea with expiration dates ranging from 2027 to 2034. Our patent portfolio is outlined below:

Selective Immunoproteasome Inhibitors

PRTX-019—Initial composition of matter patent covering selective immunoproteasome inhibitors, which also covers ONX 0914, our tool compound found in multiple publications. We have issued patents in the United States, Australia, Canada, China, Europe, Japan, Mexico, Singapore and South Korea. The 20-year term of this family is June 2027, absent any patent term extensions available.

PRTX-039—composition of matter patent covering selective immunoproteasome inhibitors, including selective LMP7 inhibitors and dual LMP7/LMP2 inhibitors. We have issued patents in the United States, Europe, Eurasia, Australia, China, Columbia, Saudi Arabia and Singapore. This patent covers KZR-616 and its closely related analogs. The 20-year term of this family is March 2034, absent any patent term extensions available.

PRTX-041—composition of matter patent covering selective immunoproteasome inhibitors of the LMP2 subunit. We have issued patents in the United States, Europe, Eurasia, China, Mexico and Singapore. The 20-year term of this family is March 2034, absent any patent term extensions available.

KZR-616 Synthetic Process – patent application pending in numerous jurisdictions, directed to process for preparing KZR-616. No patents have been issued yet, but the 20-year term for this family is expected to be June 2037, absent any patent term extensions available.

KZR-616 Salts and Polymorphs– patent application pending in numerous jurisdictions, directed to various salts and polymorphs of KZR-616, including the clinical salt form. No patents have been issued yet, but the 20-year term for this family is expected to be June 2037, absent any patent term extensions available.

Proteasome Inhibitor Combination Therapies – Two patent families directed to combination therapies for immunoproteasome inhibitors are pending, with no issued patents yet. A first, directed to the combination of selective LMP7 and LMP2 inhibitors, that is, the combination of PRTX-039 + PRTX-041 inhibitors, for the treatment of autoimmune diseases is expected to have a 20-year term of September 2038, absent any patent term extensions available. The second is directed to the combination of KZR-616 and related analogs and immunomodulator drugs, such as mycophenolate mofetil, for the treatment of lupus, lupus nephritis and other autoimmune diseases. The 20-year term of this family is expected to be August 2038, absent any patent term extensions available.

KZR-616 Formulation – patent application directed to formulations of KZR-616, filed provisionally in October 2018. We expect the non-provisional application to be filed in October 2019. No patents have issued yet, but the 20-year term of this family is expected to be October 2039, absent any patent term extensions available.

We expect to file future applications for new composition of matter for second generation selective inhibitors of the immunoproteasome pending results from ongoing drug discovery efforts.

Protein Secretion Modulators

Our scientists and the laboratory of our co-founder, Dr. Jack Taunton of UCSF, have developed a significant level of proprietary knowledge around Sec61 translocon biology, the pharmacology and toxicology of protein secretion inhibitors, and know-how for determination of optimal properties for product candidates. We have filed three applications around protein secretion inhibitors directed to different scaffolds currently being pursued by us alone or in collaboration with the Taunton Lab at UCSF and expect to file additional applications in this area in 2019.

Patent Term and Term Extensions

Individual patents have terms for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office, or the USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the restoration period cannot extend the patent term beyond 14 years from FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. All taxes or annuities for a patent, as required by the USPTO and various foreign jurisdictions, must be timely paid in order for the patent to remain in force during this period of time.

The actual protection afforded by a patent may vary on a product by product basis, from country to country, and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Our patents and patent applications are subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Trademarks and Know-How

In connection with the ongoing development and advancement of our products and services in the United States and various international jurisdictions, we seek to create protection for our marks and enhance their value by pursuing trademarks and service marks where available and when appropriate. In addition to patent and trademark protection, we rely upon know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants, and invention assignment agreements with our employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local levels, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products, such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

KZR-616 is designed to be delivered to patients via a self-administered dual-chamber system. In the United States, products composed of components that would normally be regulated by different centers at the FDA are known as combination products. While we expect that KZR-616 will be regulated as a drug and its delivery device will be evaluated with it as a single product, we cannot be certain that the FDA would not require independent clearance or approval for the self-administered dual-chamber system delivery. Whether approved separately or under a single New Drug Application, or NDA, our self-administered dual-chamber system will have to meet medical device regulatory requirements, including design verification and validation and human factors testing.

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing 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 United States requirements at any time during the drug development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials, in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of an FDA inspection of selected clinical sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees; and
- FDA review and approval of the NDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the nonclinical tests,

together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some nonclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a 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

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must continue to oversee the clinical trial while it is being conducted. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. In Phase 2, the drug typically is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. In Phase 3, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the safety and efficacy of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted, at least annually, to the FDA, and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, 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 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 has been associated with unexpected serious harm to patients.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision.

In addition, under the Pediatric Research Equity Act, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application 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. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCP requirements.

The testing and approval process for an NDA requires substantial time, effort and financial resources, and takes several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval of an NDA on a timely basis, or at all.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000, there is no reasonable expectation that sales of the drug in the United States will be

sufficient to offset the costs of developing and making the drug available in the United States. Orphan drug designation must be requested before submitting an NDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If the FDA approves a sponsor's marketing application for a designated orphan drug for use in the rare disease or condition for which it was designated, the sponsor is eligible for a seven-year period of marketing exclusivity, during which the FDA may not approve another sponsor's marketing application for a drug with the same active moiety and intended for the same use or indication as the approved orphan drug, except in limited circumstances, such as if a subsequent sponsor demonstrates its product is clinically superior. During a sponsor's orphan drug exclusivity period, competitors, however, may receive approval for drugs with different active moieties for the same indication as the approved orphan drug, or for drugs with the same active moiety as the approved orphan drug, but for different indications. Orphan drug exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for a drug with the same active moiety intended for the same indication before we do, unless we are able to demonstrate that grounds for withdrawal of the orphan drug exclusivity exist, or that our product is clinically superior. Further, if a designated orphan drug receives marketing approval for an indication broader than the rare disease or condition for which it received orphan drug designation, it may not be entitled to exclusivity.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted. If the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that are designed to treat serious conditions, and if approved, would provide a significant improvement in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the current PDUFA agreement, these six- and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has 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, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, a sponsor can request designation of a product candidate as a "breakthrough therapy." 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 or life-threatening disease

or 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. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications, manufacturing changes or other labeling claims, are subject to further testing requirements and prior FDA review and approval. There also are continuing annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as application fees for supplemental applications with clinical data.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the 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 mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution 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 trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product 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 may be promoted only for the approved indications and in accordance with the provisions of the approved label, although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. 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.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Federal and State Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state healthcare laws and regulations restrict business practices in the biopharmaceutical industry. These laws may impact, among other things, our current and future business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business or financial arrangements and relationships with healthcare providers and other parties through which we market, sell and distribute our products for which we obtain marketing approval. These laws include anti-kickback and false claims laws and regulations, data privacy and security, and transparency laws and regulations, including, without limitation, those laws described below.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, formulary managers and others, on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, 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 federal civil False Claims Act or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Federal false claims laws, including the federal civil False Claims Act, prohibits any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal civil and criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing

or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, imposes specified requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which are not pre-empted by HIPAA, differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The federal Physician Payments Sunshine Act requires certain manufacturers of 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 report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, as well as state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing. Additional state and local laws also require the registration of pharmaceutical sales and medical representatives.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, criminal and civil monetary penalties, damages, fines, imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, data privacy and security laws, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Coverage and Reimbursement

The future commercial success of our product candidates or any of our collaborators' ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for our product candidates. Government health administration authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government, through the Medicare or Medicaid programs, provides reimbursement for such treatments. In the United States, the European Union, or EU, and other potentially significant markets for our product candidates, government authorities and third party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in

average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the EU will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general.

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for medical products. For example, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of healthcare services and products. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one third-party payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party payor reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products and product candidates or exclusion of our product candidates from coverage. The cost containment measures that third-party payors and healthcare providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party payor coverage or adequate reimbursement for our product candidates in whole or in part.

Impact of Healthcare Reform on our Business

The United States and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, if approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts, which include major legislative initiatives to reduce the cost of care through changes in the healthcare system, including limits on the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded healthcare programs, and increased governmental control of drug pricing.

There have been several U.S. government initiatives over the past few years to fund and incentivize certain comparative effectiveness research, including creation of the Patient-Centered Outcomes Research Institute under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payors do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our product on a profitable basis.

The PPACA became law in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers. Among other measures that may have an impact on our business, the PPACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Additionally, the PPACA extends manufacturers' Medicaid rebate liability, expanded eligibility criteria for Medicaid programs, and expands entities eligible for discounts under the Public Health Service pharmaceutical pricing program. Since enacted, there have

been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA, and we expect such challenges and amendments to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the PPACA will impact the PPACA.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, then President Obama signed into law the Budget Control Act of 2011, as amended, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and, following passage of subsequent legislation, including the BBA, will continue through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was enacted and, 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 and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contained further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. For example, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. On January 31, 2019, the U.S. Department of Health and Human Services, Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

As a result of the PPACA, Medicare payments are increasingly tied to quality of care and value measures, and reporting of related data by providers such as physicians and hospitals. So called "value based reimbursement" measures may present challenges as well as potential opportunities for biopharmaceutical manufacturers. Medicare incentives for providers meeting certain quality measures may ultimately prove beneficial for manufacturers that are able to establish that their products may help providers to meet such measures. However, manufacturers' ability to market their drug products based on quality or value is highly regulated and not always permissible. In addition, potentially decreased Medicare reimbursement to those providers that fail to adequately comply with quality reporting requirements could translate to decreased resources available to purchase products and may negatively impact marketing or utilization of our product candidates if they are approved for marketing. We cannot predict at this time what impact, if any, the longer-term shift towards value based reimbursement will have on any of our product candidates in either the Medicare program, or in any other third party payor programs that may similarly tie payment to provider quality.

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

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our product candidates. For example, in the EU, we must obtain authorization of a clinical trial application, or CTA, in each member state in which we intend to conduct a clinical trial. Whether or not we obtain FDA approval for a drug, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the drug in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Employees

As of December 31, 2018, we had 24 full-time employees, 18 of whom were primarily engaged in research and development activities and 9 of whom had an M.D. or Ph.D. degree. None of our employees is represented by a labor union and we consider our employee relations to be good.

Corporate Information

We were incorporated under the laws of the State of Delaware on February 19, 2015. Our principal executive offices are located at 4000 Shoreline Court, Suite 300, South San Francisco, California 94080, and our telephone number is (650) 822-5600. In January 2016, we incorporated our wholly owned Australian subsidiary, Kezar Life Sciences Australia Pty Ltd, which is a proprietary company limited by shares.

Available Information

Our website address is www.kezarlifesciences.com. We make available on our website, free of charge, our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q and 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, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. The SEC maintains a website that

contains reports, proxy and information statements and other information regarding our filings at www.sec.gov. The information found on our website is not incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

Item 1A. Risk Factors.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Annual Report on Form 10-K, including our financial statements and related notes hereto, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In these circumstances, the market price of our common stock could decline; and you may lose all or part of your investment. We cannot assure you that any of the events discussed below will not occur.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.

Since inception in February 2015, we have incurred significant operating losses. Our net loss was $8.5 million and $23.2 million for the years ended December 31, 2017 and 2018, respectively. As of December 31, 2018, we had an accumulated deficit of $49.2 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Since inception, we have devoted substantially all of our efforts to research and preclinical and clinical development of our product candidates, as well as to expanding our management team and infrastructure. It could be several years, if ever, before we have a commercialized drug. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue the ongoing and planned development of KZR-616;
- seek to discover and develop additional product candidates;
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- establish a sales, marketing, manufacturing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- continue to build a portfolio of product candidates through the acquisition or in-license of drugs, product candidates or technologies;
- seek marketing approvals for KZR-616 and any future product candidates that successfully complete clinical trials;
- maintain, protect and expand our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- implement operational, financial and management systems;
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel; and
- incur additional legal, accounting and other expenses associated with operating as a public company.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical products and development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses could increase and profitability could be further delayed if we decide to or are required by regulatory authorities to perform studies or trials in addition to those currently expected, or if there are any delays in the development, or in the completion of any planned or future preclinical studies or clinical trials of our current and future product candidates. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing KZR-616 and any future product candidates.

Even 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 raise capital, maintain our research and development efforts, expand our business or continue our operations.

We have a limited operating history and have never generated any revenue from product sales, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage company founded in February 2015, and our operations to date have been largely focused on raising capital and undertaking preclinical studies and conducting early-stage clinical trials for KZR-616. As an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with any future collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, KZR-616 and any future product candidates. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate revenue from product sales depends heavily on our, or any future collaborators', success in:

- timely and successfully completing preclinical and clinical development of KZR-616 and any future product candidates;
- obtaining regulatory approvals for KZR-616 and any future product candidates for which we successfully complete clinical trials;
- launching and commercializing any product candidates for which we obtain regulatory approval by establishing a sales force, marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- qualifying for and obtaining coverage and adequate reimbursement by government and third-party payors for any product candidates for which we obtain regulatory approval, both in the United States and internationally;
- developing, validating and maintaining commercially viable, sustainable, scalable, reproducible and transferable manufacturing processes for KZR-616, a self-administered dual-chamber system for KZR-616 and any future product candidates that are compliant with current good manufacturing practices, or cGMP;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate amount and quality of starting materials, drug substance, drug product and drug delivery devices and services to support clinical development, as well as the market demand for KZR-616 and any future product candidates, if approved;
- obtaining market acceptance, if and when approved, of KZR-616 or any future product candidate as a viable treatment option by physicians, patients, third-party payors and others in the medical community;
- effectively addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations pursuant to such arrangements;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- securing appropriate pricing in the United States and internationally.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We may need to eventually transition from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

We will require substantial additional capital to finance our operations, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, reduce or terminate certain of our product development programs or other operations.

Our operations have consumed substantial amounts of cash since our inception. We expect our expenses to increase in connection with our ongoing and planned activities, particularly as we continue to develop and potentially commercialize our product candidates, in addition to costs associated with the acquisition or in-licensing of any additional product candidates we may pursue. Our expenses could increase beyond expectations if the U.S. Food and Drug Administration, or FDA, or other regulatory authorities require us to perform clinical and other studies in addition to those that we currently anticipate. In addition, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to sales, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company.

As of December 31, 2018, our cash, cash equivalents and marketable securities was $107.4 million. We believe that our existing cash, cash equivalents and marketable securities will fund our current operating plans through at least the next 12 months from the date the financial statements were issued. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.

In any event, we will require substantial additional capital to develop a delivery system for KZR-616, conduct additional clinical trials, seek regulatory approval and commence commercialization of KZR-616 or any future product candidates. Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize KZR-616 and any future product candidates.

If we do not raise additional capital in sufficient amounts, or on terms acceptable to us, we may be prevented from pursuing discovery, development and commercialization efforts, which will harm our business, operating results and prospects.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. In addition, we may issue equity or debt securities as consideration for obtaining rights to additional compounds.

Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could negatively impact our ability to conduct our business. If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

We may be required to make significant payments in connection with our license agreement with Onyx Therapeutics, Inc., or Onyx, for KZR-616 and other compounds.

In June 2015, we acquired rights to KZR-616, pursuant to a license agreement with Onyx, or the Onyx license agreement. Under the Onyx license agreement, we are subject to significant obligations, including payment obligations triggered upon achievement of specified milestones and royalties on licensed product sales, as well as other material obligations. We are obligated to pay Onyx milestone payments up to an aggregate of $172.5 million upon the achievement of certain development, regulatory and sales milestone events. In addition, we are obligated to pay Onyx tiered royalties based on net sales of KRZ-616. If these payments become due, we may not have sufficient funds available to meet our obligations and our development efforts may be harmed.

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

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could negatively impact our future cash flows.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was signed into law. The Tax Act contains, among other things, significant changes to corporate taxation, including (i) a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (ii) a limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), (iii) a limitation of the deduction for net operating losses to 80% of current year taxable income in respect of net operating losses generated during or after 2018 and elimination of net operating loss carrybacks, (iv) a one-time tax on offshore earnings at reduced rates regardless of whether they are repatriated, (v) immediate deductions for certain new investments instead of deductions for depreciation expense over time, and (vi) a modification or repeal of many business deductions and credits, including a reduction of the Orphan Drug Credit from 50% to 25% of eligible clinical costs. Any federal NOLs incurred in 2018 and in future years may now be carried forward indefinitely pursuant to the Tax Act. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. We will continue to examine the impact the Tax Act may have on our business and financial condition.

Risks Related to the Development and Commercialization of Our Product Candidates

Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of KZR-616 and any future product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate revenue will be adversely affected.

The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. 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. KZR-616 is currently our only product candidate. We have not obtained regulatory approval for KZR-616 or any product candidate, and it is possible that neither KZR-616 nor any product candidates we may seek to develop in the future will ever obtain regulatory approval. Neither we nor any future collaborator is permitted to market KZR-616 or any future drug product candidates in the United States or abroad until we receive regulatory approval from the FDA or applicable foreign regulatory agency.

Prior to obtaining approval to commercialize KZR-616 and any other drug product candidate in the United States or abroad, we must demonstrate with substantial evidence from well controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program. In addition, the FDA typically refers applications for novel drugs, like KZR-616 and potentially other of our future product candidates, to an advisory committee comprising outside experts. The FDA is not bound by the recommendation of the advisory committee, but it considers such recommendation when making its decision.

Of the large number of products in development, only a small percentage successfully complete the FDA or comparable foreign regulatory authority approval processes and are commercialized. The lengthy approval or marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval or marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We have invested a significant portion of our time and financial resources in the development of KZR-616. Our business is dependent on our ability to successfully complete development of, obtain regulatory approval for, and, if approved, successfully commercialize KZR-616 and any future product candidates in a timely manner.

Even if we eventually complete clinical testing and receive approval of a new drug application, or NDA, or foreign marketing application for KZR-616 or any future product candidates, the FDA or the comparable foreign regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authorities also may approve or authorize for marketing a product candidate for a more limited indication or patient population that we originally request, and the FDA or comparable foreign regulatory authorities may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, the FDA and comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Furthermore, even if we obtain regulatory approval for KZR-616 and any future product candidates, we will still need to develop a commercial organization, establish a commercially viable pricing structure and obtain approval for adequate reimbursement from third-party and government payors. If we are unable to successfully commercialize KZR-616 and any future product candidates, we may not be able to generate sufficient revenue to continue our business.

We may not be successful in our efforts to expand our pipeline of product candidates.

A key element of our strategy is to build a pipeline of product candidates and to progress these product candidates through clinical development for the treatment of autoimmune indications, oncology, and immuno-oncology. We may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of safety, tolerability, efficacy or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval, achieve market acceptance or obtain reimbursements from third-party payors. If we do not successfully develop and commercialize product candidates or collaborate with others to do so, we will not be able to generate product revenue which could significantly harm our financial position and adversely affect the trading price of our common stock.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trial results and we cannot assure you that any on-going, planned or future clinical trials will lead to results sufficient for the necessary regulatory approvals.

Success in preclinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and early clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical studies and earlier clinical trials does not ensure that later efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

We may encounter substantial delays or difficulties in our clinical trials.

We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the FDA or other comparable regulatory authority, and we may never receive such approvals. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. 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 products.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize KZR-616 or any future product candidates, including:

- delays in reaching a consensus with regulatory authorities on design or implementation of our clinical trials;
- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or fail to return for post-treatment follow-up or we may fail to recruit suitable patients to participate in a trial;
- clinical trials of our product candidates may produce negative or inconclusive results;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates or after an inspection of our clinical trial operations, trial sites or manufacturing facilities;

- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future drug sales or other sources. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring competing drugs to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

Further, we, the FDA, other comparable regulatory authorities, or an IRB may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our investigational new drug applications, or INDs, or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenues from our product candidates may be delayed.

We may not be able to obtain or maintain orphan drug designations or exclusivity for our product candidates, which could limit the potential profitability of our product candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000, there is no reasonable expectation that sales of the drug in the United States will be sufficient to offset the costs of developing and making the drug available in the United States. If a drug with an orphan drug designation subsequently receives the first

marketing approval for use in the rare disease or condition for which it was designated, then the sponsor is eligible for a seven-year period of marketing during which the FDA may not approve another sponsor's marketing application for a drug with the same active moiety and intended for the same use or indication as the approved orphan drug, except in limited circumstances, such as if a subsequent sponsor demonstrates its product is clinically superior. During a sponsor's orphan drug exclusivity period, however, competitors may receive approval for drugs with different active moieties for the same indication as the approved orphan drug, or for drugs with the same active moiety as the approved orphan drug, but for different indications. Orphan drug exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for a drug with the same active moiety intended for the same indication before we do, unless we are able to demonstrate that grounds for withdrawal of the orphan drug exclusivity exist or that our product is clinically superior. Further, if a designated orphan drug receives marketing approval for an indication broader than the rare disease or condition for which it received orphan drug designation, it may not be entitled to exclusivity. For purposes of small molecule drugs, the FDA defines "same drug" as a drug that contains the same active moiety and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

We intend to pursue orphan drug designation for KZR-616 in orphan autoimmune indications. Obtaining orphan drug designation can be difficult, and we may not be successful in doing so. Even if we were to obtain orphan drug designation for a product candidate, that exclusivity may not effectively protect the drug from the competition of different drugs for the same condition, which could have already been approved or could be approved before or during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusive marketing rights in the United States also may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. The failure to obtain an orphan drug designation for any product candidates we may develop, the inability to maintain that designation for the duration of the applicable period, or the inability to obtain or maintain orphan drug exclusivity could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

KZR-616 is intended to be used with a self-administered dual-chamber system, which may result in additional regulatory and other risks.

Beginning in Phase 2, we expect KZR-616 will be a lyophilized product candidate, meaning it will be freeze-dried and must be reconstituted with water prior to delivery to a patient. While lyophilized products are common in the drug industry, we intend that if approved and commercialized, KZR-616 will be self-administered by patients via a self-administered dual-chamber system. There are several technical challenges we will need to solve related to use of a self-administered dual-chamber system, including whether KZR-616 is amenable to use in such a device and whether it is sufficiently stable to meet regulatory requirements. We may not be able to solve these technical challenges, which would require that patients reconstitute KZR-616 themselves prior to injection. This method for administering KZR-616 could adversely affect market acceptance of KZR-616 and make it more difficult to conduct clinical trials of KZR-616. In addition, if we have not successfully developed the self-administered dual-chamber system by the time we commence Phase 3 clinical trials for KZR-616, we may need to seek approval for KZR-616 via a different delivery system, which could require additional bio-equivalence or efficacy clinical trials.

In addition, we will need to enter into an agreement with a contract manufacturing organization, or CMO, to manufacture the self-administered dual-chamber system, and we are aware of only one company that manufactures a self-administered dual-chamber system that has received FDA approval. We may be dependent on the sustained cooperation of a third-party or collaborators to supply the devices; to conduct the studies required for approval or clearance by the applicable regulatory agencies; and to continue to meet the applicable regulatory and other requirements to maintain approval or clearance once it has been received.

We may experience delays in obtaining regulatory approval of KZR-616 with a self-administered dual-chamber system given the increased complexity of the review process when approval of the product and device is sought under a single marketing application. If delivered by a self-administered dual-chamber system, KZR-616 may be regulated as a drug/device combination product. In the United States, each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic or device. The determination whether a combination product requires a single marketing application or two separate marketing applications for each component is made by the FDA on a case-by-case basis. Although a single marketing application is generally sufficient for the approval of a combination product, the FDA may determine that separate marketing applications are necessary. This could significantly increase the resources and time required to bring a particular combination product to market. While we expect KZR-616, along with the self-administered dual-chamber system, to be subject to a single marketing application reviewed by the Center for Drug Evaluation and Research (CDER) at the FDA based on its primary mode of action as a drug, the FDA could disagree.

Failure to successfully develop or supply the device, delays in or failure of the studies conducted by us, our collaborators or third-party providers, or failure by us, our collaborators or the third-party providers to obtain or maintain regulatory approval or clearance of the device could result in increased development costs, delays in or failure to obtain regulatory approval and associated delays in KZR-616 reaching the market. Further, failure to successfully develop or supply the device, or to gain or maintain its approval, could adversely affect sales of KZR-616.

If we are not successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

A key element of our strategy is to discover, develop and potentially commercialize a portfolio of product candidates to treat autoimmune diseases and oncology. We focus our clinical development of KZR-616 on autoimmune diseases with high, unmet medical needs to leverage the development and regulatory paths available for first-in-class or best-in-class agents. Efforts to identify and develop product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development, approved products or commercial revenues for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render any product candidates we develop obsolete;
- any product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by physicians, patients, the medical community or third-party payors.

We have limited financial and management resources and, as a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater market potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in circumstances under which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. If we are unsuccessful in identifying and developing additional product candidates or are unable to do so, our business may be harmed.

Clinical trials are very expensive, time consuming and difficult to design and implement.

Our product candidates will require clinical testing before we are prepared to submit an NDA for regulatory approval. We cannot predict with any certainty if or when we might submit an NDA for regulatory approval for any of our product candidates or whether any such NDA will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with our proposed endpoints for any future clinical trial of our product candidates, which may delay the commencement of our clinical trials. In addition, we may not succeed in developing and validating disease-relevant clinical endpoints based on insights regarding biological pathways for the disorders we are studying. The clinical trial process is also time consuming. We estimate that the successful completion of clinical trials of our product candidates will take several years to complete. Furthermore, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials.

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

Identifying and qualifying patients to participate in our clinical trials is critical to our success. We intend to develop KZR-616 to address several autoimmune diseases with high degrees of unmet medical need, including lupus nephritis and idiopathic inflammatory myopathies, where we have planned initial Phase 2 clinical trials, as well as other rare autoimmune indications. If the actual number of patients with these disorders is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of KZR-616 and any future product candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data, the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the trial. Because our focus includes rare disorders, there are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. In addition, we may rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur. In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects or patients. Many times, side effects are only detectable after investigational drugs are tested in large-scale pivotal trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that KZR-616 or any future product candidates has side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition.

Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed and our ability to generate revenue through their sale may be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if any of our product candidates receive marketing approval, the FDA could require us to include a black box warning in our label or adopt a REMS to ensure that the benefits outweigh the risks, which may include, among other things, a Medication Guide outlining the risks of the drug for distribution to patients and a communication plan to healthcare practitioners. Furthermore, if we or others identify undesirable side effects caused by our product candidates during development or after obtaining U.S. regulatory approval several potentially significant negative consequences could result, including:

- regulatory authorities may not permit us to initiate our studies or could put them on hold;
- regulatory authorities may not approve, or may withdraw, their approval of the product;
- regulatory authorities may require us to recall the product;
- regulatory authorities may add new limitations for distribution and marketing of the product;
- regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered or modify the product in some other way;
- we may be required to implement a REMS program;
- the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved. In addition, these events could substantially increase the costs of commercializing our product candidates and could significantly harm our business, prospects, financial condition and results of operations.

Interim "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary data from our clinical trials. Interim data from clinical trials that we may complete 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. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

We may explore strategic collaborations that may never materialize, or we may be required to relinquish important rights to and control over the development and commercialization of our product candidates to any future collaborators.

Over time, our business strategy includes acquiring or in-licensing small molecule compounds directed at autoimmune or cancer indications. As a result, we intend to periodically explore a variety of possible strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations can be complicated and time consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

Future collaborations could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our stockholders' percentage ownership of our company;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- strategic collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

If the market opportunities for KZR-616 and any future product candidates are smaller than we believe they are, our business may suffer.

We currently focus our drug development of KZR-616 on treatments of autoimmune diseases. Our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product candidates. Our projections of both the number of people who have these disorders, as well as the subset of people with these disorders who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these disorders. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or access. If the market opportunities for our product candidates are smaller than we estimate, our business and results of operations could be adversely affected.

We face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.

The development and commercialization of new drugs is highly competitive. We face competition with respect to KZR-616 and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of product candidates for the treatment of the indications that we are pursuing. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

More established companies may have a competitive advantage over us due to their greater size, resources and institutional experience. In particular, these companies have greater experience and expertise in securing reimbursement, government contracts and relationships with key opinion leaders, conducting testing and clinical trials, obtaining and maintaining regulatory approvals and distribution relationships to market products and marketing approved drugs. These companies also have significantly greater research and marketing capabilities than we do. If we are not able to compete effectively against existing and potential competitors, our business and financial condition may be harmed.

As a result of these factors, our competitors may obtain regulatory approval of their drugs before we are able to, which may limit our ability to develop or commercialize our product candidates. Our competitors may also develop therapies that are safer, more effective, more widely accepted or less expensive than ours, or may be more successful than we in manufacturing and marketing their drugs. These advantages could render our product candidates obsolete or non-competitive before we can recover the costs of such product candidates' development and commercialization.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if KZR-616 or any future product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if KZR-616 or any future product candidates receive marketing approval, they may fail to gain market acceptance by physicians, patients, third-party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant drug revenue and may not become profitable. The degree of market acceptance of KZR-616 or any future product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments and therapies;
- the effectiveness of sales and marketing efforts;
- the strength of our relationships with patient communities;
- the cost of treatment in relation to alternative treatments and therapies, including any similar generic treatments;
- our ability to offer such drug for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of the drug together with other medications.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business. In addition, our rights to receive milestone payments and royalties related to KZR-616 and other product candidates will depend on our collaborators' abilities to achieve market acceptance of those product candidates.

Even if we obtain regulatory approval for KZR-616 or any future product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain regulatory approvals for KZR-616 or any future product candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. For example, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. Additionally, any regulatory approvals that we receive for KZR-616 or any future product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and surveillance to monitor the quality, safety and efficacy of the drug. Such regulatory requirements may differ from country to country depending on where we have received regulatory approval.

In addition, drug manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug,

the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of KZR-616 or any future product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or comparable foreign marketing application or any supplements thereto submitted by us or our partners;
- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize KZR-616 or any future product candidates and harm our business, financial condition, results of operations and prospects.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and to spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented and the extent to which they will affect the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell KZR-616 or any future product candidates, we may not be successful in commercializing KZR-616 or any future product candidates, if and when they are approved.

To successfully commercialize any product candidate that may result from our development programs, we will need to build out our sales and marketing capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract sales force to market any product candidate we may develop will be expensive and time-consuming and could delay any drug launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may seek to enter into collaborations with other entities to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any current or future collaborators do not commit sufficient resources to commercialize our product candidates, or we are unable to develop the necessary capabilities on our own, we may be unable to generate sufficient revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We will likely also face competition if we seek third parties to assist us with the sales and marketing efforts of KZR-616 and any future product candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Even if we obtain and maintain approval for KZR-616 or any future product candidates from the FDA, we may never obtain approval for KZR-616 or any future product candidates outside of the United States, which would limit our market opportunities and could harm our business.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of KZR-616 and any future product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable foreign regulatory authorities also must approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for any product candidates, if approved, is also subject to approval. Obtaining approval for KZR-616 and any future product candidates in the European Union from the European Commission following the opinion of the European Medicines Agency, if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a product candidate is approved, the FDA or the European Commission, as the case may be, may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of 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 KZR-616 and any future product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for our product candidates may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of KZR-616 and any future product candidates will be harmed and our business, financial condition, results of operations and prospects could be harmed.

We will be required to obtain international regulatory approval to market and sell our product candidates outside of the United States.

We anticipate marketing our product candidates, if approved, outside of the United States. In order to market any of our product candidates outside of the United States, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The requirements for approval differ from country to country and approval in one country, including approval by the FDA in the United States, does not ensure approval by the applicable regulatory authorities in any other country. As a result, we may not obtain foreign regulatory approvals on a timely basis, if at all. A failure or delay in obtaining regulatory approval in one jurisdiction could have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in foreign jurisdictions could harm our business.

If we seek approval to commercialize KZR-616 or any future product candidates outside of the United States, a variety of risks associated with international operations could harm our business.

If we seek approval of KZR-616 or any future product candidates outside of the United States, we expect that we will be subject to additional risks in commercialization including:

- different regulatory requirements for approval of therapies in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in and outside of Europe with which we will need to comply. Many biopharmaceutical companies have found the process of marketing their own products in foreign countries to be very challenging.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of KZR-616 and any future product candidates in clinical trials and may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;

- withdrawal of clinical trial participants;
- increased insurance costs;
- the inability to commercialize any product candidate that we may develop; and
- injury to our reputation and significant negative media attention.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Regulatory Compliance

Our relationships with customers, physicians, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, formulary managers and others, on the other hand. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation;
- federal civil and criminal false claims laws, including, without limitation, the federal civil False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, implicate the federal civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal civil and criminal statutes that prohibit, among other things, a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private). In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization on health plans, health care clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates that perform certain services involving the use or disclosure of individually identifiable health information;

- federal transparency laws, including the federal Physician Payments Sunshine Act, that require certain manufacturers of 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 report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (i) payments or other "transfers of value" made to physicians and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws, state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and state and local laws that require the registration of pharmaceutical sales and medical representatives, or that otherwise restrict payments that may be made to healthcare providers; as well as state and foreign laws that 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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

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 civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. 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. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Coverage and adequate reimbursement may not be available for KZR-616 or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which coverage and reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One third-party payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each third-party payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a third-party payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or

part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize KZR-616 or any future product candidates that we develop.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The PPACA, among other things: (i) addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) established annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; and (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Some of the provisions of the PPACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Act included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA and our business. We continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015 which will be fully implemented in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement. Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contained further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. For example, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. On January 31, 2019, the U.S. Department of Health and Human Services, Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and 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 drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party 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 products.

Risks Related to Our Dependence on Third Parties

We will rely on third parties to produce clinical and commercial supplies of KZR-616 and any future product candidates.

Although we have small-scale internal manufacturing capabilities for characterization and preclinical assessment purposes, we do not expect to own or operate, facilities for drug manufacturing, storage and distribution, or testing. We will be dependent on third parties to manufacture the clinical supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs for manufacture of both active drug substances and finished product candidates, and the quality system regulation, or QSR, applicable to the self-administered dual-chamber system for KZR-616. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict

regulatory requirements of the FDA or others, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have no 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 regulatory approval for or market our product candidates, if approved.

Further, we also will rely on third-party manufacturers to supply us with sufficient quantities of our product candidates, including KZR-616, to be used, if approved, for commercialization. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- our third-party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our third-party manufacturers may fail to comply with cGMP-compliance and other inspections by the FDA or other comparable regulatory authorities;
- our inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for drug components;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- our third-party manufacturers may not devote sufficient resources to our product candidates;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

Any of these events could lead to clinical trial delays, failure to obtain regulatory approval or impact our ability to successfully commercialize our current or any future product candidates once approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure, or total or partial suspension of production.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers'

facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry hazardous waste insurance coverage.

We rely on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We do not currently have the ability to independently conduct any clinical trials. We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our preclinical studies and clinical trials, and we expect to have limited influence over their actual performance. We rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the good laboratory practices, or GLPs, and GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities in the form of International Conference on Harmonisation guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our reliance on third parties to conduct clinical trials will result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with CROs and other third parties can be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Such parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues; or
- undergo changes in priorities or become financially distressed.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, fail to comply with regulatory requirements, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be

delayed. While we will have agreements governing their activities, our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology.

If our relationship with any of these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, financial condition and prospects.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of KZR-616 and any future product candidates.

Risks Related to Our Intellectual Property

If we are unable to obtain adequate protection for our proprietary know-how or obtain and maintain patent protection for KZR-616 or any future product candidates, or if the scope of the patent protection obtained is not sufficiently broad, or if our patents are insufficient to protect our product candidates for an adequate amount of time, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to KZR-616 and any future product candidates. We seek to protect our proprietary position by, among other methods, filing patent applications in the United States and abroad related to our current and future development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

We acquire, in-license and file patent applications directed to our product candidates in an effort to establish intellectual property positions directed to their compositions of matter as well as uses of these product candidates in the treatment of diseases. Our intellectual property includes patents and patent applications that we own as well as patents and patent applications that we in-license. For example, we have a field-specific exclusive license under the Onyx license agreement to some of our patent applications and patents relating to KZR-616.

We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if approved. In addition, we cannot be sure that any of our pending patent applications or pending trademark applications will issue or that, if issued, they have or will issue in a form that will be advantageous to us. The United States Patent and Trademark Office, or the USPTO, international patent offices or judicial bodies may deny or significantly narrow claims made under our patent applications and our issued patents may be successfully challenged, may be designed around, or may otherwise be of insufficient scope to provide us with protection for our commercial products.

It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, patent prosecution is a lengthy process, during which the scope of the

claims initially submitted for examination by the USPTO may be significantly narrowed by the time they issue, if issued at all. The claims of our issued patents or patent applications when issued may not cover our current or future product candidates, or even if such patents provide coverage, the coverage obtained may not provide any competitive advantage. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current or any future product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which 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 current or any future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and companion diagnostic under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for KZR-616 or any future product candidates, it could dissuade companies from collaborating with us to develop and commercialize product candidates and future drugs and threaten our ability to commercialize, future drugs. Any such outcome could have a negative effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Furthermore, other parties may have developed or may develop technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our patent applications or issued patents, with respect to either the same methods or formulations or the same subject matter, in either case, that we may rely upon to dominate our patent position in the market. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drugs, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to the United States patent law. These include provisions that affect the way patent applications are prosecuted and may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by or against us related to our patent rights. The Leahy-Smith Act, in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. 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 harm our business and financial condition.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us without payment to us, or result in our inability

to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize KZR-616 or any future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party submission of prior art to the USPTO challenging the priority of an invention claimed within one of our patents, which submissions may also be made prior to a patent's issuance, precluding the granting of any of our pending patent applications. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, or limit the duration of the patent protection of our technology and drugs. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years from the earliest filing date of a non-provisional patent application. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for KZR-616 or any future product candidates, we may be open to competition from generic versions of such drugs. Given 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 drugs similar or identical to ours.

Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. For example, a third-party may develop a competitive drug that provides benefits similar to one or more of our product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, or if the breadth, strength or term (including any extensions or adjustments) of protection provided by the patents and patent applications we hold or pursue with respect to our product candidates or any future product candidates is successfully challenged, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates or any future product candidates under patent protection would be reduced.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will have to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our outside counsel or our licensing partners to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, 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 licensors fail to maintain the patents and patent applications covering our products or technologies, we may not be able to stop a competitor from marketing products that are the same as or similar to our product candidates, which would have a material adverse effect on our business. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance 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. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

In addition, if we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patents. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, any of the foregoing could expose us to liability to the applicable patent owner.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new product candidates such as KZR-616, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, 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 be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their drug earlier than might otherwise be the case.

Intellectual property rights do not necessarily address all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents, should they issue, that we own or control;
- we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or control;
- we might not have been the first to file patent applications covering certain of our inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or control may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of our future collaborators to develop, manufacture, market and sell KZR-616 and any future product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to KZR-616 and any future product candidates and technology, including interference proceedings, post grant review and inter partes review before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize KZR-616 and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Many companies and research institutions have filed, and continue to file, patent applications related to selective immunoproteasome inhibitors. Some of these patent applications have already been allowed or issued, and others may issue in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third party patents or patent applications, or we may incorrectly conclude that a third party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes our product candidate infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technology. Under any such license, we would most likely be required to pay various types of fees, milestones,

royalties or other amounts. Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may also pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. 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 or other intellectual property right. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from manufacturing and commercializing KZR-616 or any future product candidates or force us to cease some or all of our business operations, which could materially harm our business. Even if we are successful in defending against such claims, litigation can be expensive and time consuming and would divert management's attention from our core business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach the Onyx license agreement or any of the other agreements under which we acquired, or will acquire, our product candidates, we could lose the ability to continue the development and commercialization of the related product.

The licensing of intellectual property is of critical importance to our business and to our current and future product candidates, and we expect to enter into additional such agreements in the future.

In particular, our immunoproteasome program, including KZR-616, is dependent on our license agreement with Onyx. Pursuant to the Onyx license agreement, Onyx granted us an exclusive license under certain patent rights, and a non-exclusive license to certain know-how, controlled by Onyx and relating to our immunoproteasome program, to develop, manufacture or commercialize certain types of compounds, including KZR-616, that are selective for the immunoproteasome, for any and all uses other than those related to the diagnosis and/or treatment in humans of cancerous or pre-cancerous diseases and/or conditions, including those related to hematological diseases and/or conditions.

The licensed compounds, including KZR-616, are selective for the immunoproteasome and therefore are not known or believed (based on scientific literature and the Company's own research and development activities) to have any application in cancer or pre-cancerous conditions. However, notwithstanding these known characteristics of the licensed compounds, Onyx retains all rights under the licensed intellectual property rights that are not granted to the Company, and therefore Onyx retains rights under such intellectual property rights to develop and commercialize the licensed compounds in connection with the diagnosis and/or treatment in humans of cancerous or pre-cancerous diseases and/or conditions, including those related to hematological diseases and/or conditions, and also has the rights to transfer these rights to a third-party. If one or more of the licensed compounds were found to have any application in cancer or pre-cancerous indications, and if Onyx or a third-party commercialized these compounds in such indications in forms that are commercially interchangeable with our licensed compounds during time periods in which we also commercialize such licensed compounds within our licensed field, sales of such compounds for such cancer and pre-cancerous indications could result in a threat of off-label use of such compounds in our licensed field, potentially diminishing our sales of the applicable licensed compounds in our licensed field.

The Onyx license agreement may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. Specifically, under the Onyx license agreement, Onyx has a right of first negotiation under certain circumstances to obtain a license or a similar transfer of rights, if we are seeking to out-license rights to develop and/or commercialize certain licensed products.

Disputes may arise between us and any of these counterparties regarding intellectual property rights that are subject to such agreements, including, but not limited to:

- the scope of rights granted under the agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign our license; and
- the effects of termination.

These or other disputes over intellectual property that we have licensed (or will license or acquire in the future) may prevent or impair our ability to maintain our current arrangements on acceptable terms, or may impair the value of the arrangement to us. Any such dispute could have an adverse effect on our business.

If we fail to meet our obligations under these agreements in any material respect, the counterparty may have the right to terminate the respective agreement. Any uncured, material breach under a license could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for each of our product candidates. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the technology licensed to or acquired by us, we may not be able to do so in a timely manner, at an acceptable cost or at all.

Furthermore, certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is or will be no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license, and such a license may not be on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect KZR-616 and any future product candidates.

The United States has recently enacted and implemented wide ranging patent reform legislation. 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering KZR-616 and any future product candidates throughout the world would be prohibitively expensive. Competitors may use our 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 may obtain patent protection but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Since we rely on third parties to discover, develop, manufacture or commercialize KZR-616 or any future product candidates, or if we collaborate with third parties for the development of KZR-616 or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally obtained and is using our

trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for KZR-616 and have not yet begun the process of applying to register trademarks for KZR-616 or any other product candidate. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with KZR-616 or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, 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 these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us.

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

We are highly dependent on the services of our Chief Executive Officer, John Fowler, and our President and Chief Scientific Officer, Dr. Christopher Kirk, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

We are highly dependent on our Chief Executive Officer, John Fowler, and our President and Chief Scientific Officer, Dr. Christopher Kirk. Each of them may currently terminate their employment with us at any time. The loss of the services of either of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining other senior executives, qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2018, we had 24 full-time employees. As the clinical development of our product candidates progresses, we also expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we

manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks on our technology environment. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our, our third-party vendors' and/or business partners' information technology systems or other similar data security incidents could adversely affect our business operations or result in the loss, misappropriation, or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, 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 to recover or reproduce the data.

There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including but not limited to personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and/or state breach notification laws and foreign law equivalents, subject us to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us, and result in significant legal and financial exposure and/or reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security-related legal or other obligations to third parties, or any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report

financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. 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 government 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 result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

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

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary drugs, intellectual property rights, technologies or businesses, as deemed appropriate to carry out our business plan. 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;
- assimilation of operations, intellectual property and drugs of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing drug programs and initiatives in pursuing such a strategic partnership, 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 drugs or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or drugs sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we engage in future acquisitions or strategic partnerships, 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 drugs that may be important to the development of our business.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be volatile and fluctuate substantially, and you could lose all or part of your investment.

The market price of our common stock is likely to be volatile. The stock market in general and the market for biopharmaceutical and pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be

able to sell your common stock at or above the price paid for the shares. In addition to the factors discussed in this "Risk Factors" section, the market price for our common stock may be influenced by the following:

- the commencement, enrollment or results of our planned or future clinical trials of KZR-616 and any future product candidates or those of our competitors;
- the success of competitive drugs or therapies;
- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to KZR-616 and any future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate drug supply for any approved drug or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

A public market may not develop or be liquid enough for you to sell your shares quickly or at market price.

Prior to our initial public offering, or IPO, in June 2018, there had not been a public market for our common stock. If an active trading market for our common stock does not develop, you may not be able to sell your shares quickly or at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations

by selling shares of our common stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based upon our shares of our common stock outstanding as of December 31, 2018, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock do, in the aggregate, beneficially own shares representing approximately 58% of our outstanding common stock. If our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock acted together, they may be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in the management of our company in ways with which other stockholders disagree.

If research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or financial analysts publish about us or our business. Equity research analysts may discontinue research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. We do not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our shares could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We have broad discretion in the use of our cash and cash equivalents and may use them in ways in which you do not agree or in ways that do not increase the value of your investment.

Our management will have broad discretion in the application of our cash and cash equivalents, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a negative impact on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash and cash equivalents, in a manner that does not produce income or that loses value.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from 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 in the assessment of our internal control over financial reporting;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We currently take advantage of some or all of these reporting exemptions until we are no longer an EGC. We will remain an EGC until the earlier of (i) December 31, 2023, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (iii) the last day of the first fiscal year in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (iv) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We cannot predict whether investors will find our common stock less attractive because we will 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 share price may be more volatile.

In addition, under Section 107(b) of the JOBS Act, EGCs can 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, we will be subject to the same new or revised accounting standards as other public companies that are not EGCs.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, and particularly after we are no longer an EGC, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and rules subsequently implemented by the SEC and The Nasdaq Stock Market LLC have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC, we will not 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 engaged 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 internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.

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

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common

stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be affected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 ⅔% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our 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 breach of fiduciary duty;
- any action asserting a claim against us or any of our directors, officers, employees or agents arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us or any of our directors, officers, employees or agents 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, or 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.

None.

Item 2. Properties.

Our principal corporate offices are located in South San Francisco, and consists of 24,357 square feet of leased office and laboratory space, all of which is located in a single building, under a lease that expires in February 2025. We believe that our facilities are adequate to meet our current needs.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

Item 4. Mine Safety Disclosures.

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trading on The Nasdaq Global Select Market under the symbol "KZR" following our IPO on June 21, 2018. Prior to our IPO, there was no public market for our common stock.

Holders

As of March 22, 2019, there were approximately 34 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from the IPO

On June 25, 2018, we completed our IPO and issued 5,750,000 shares of our common stock at an initial offering price of $15.00 per share (inclusive of 750,000 shares of common stock pursuant to the full exercise of an overallotment option granted to the underwriters in connection with the offering). We received net proceeds from the IPO of approximately $77.7 million, after deducting underwriting discounts and commissions of approximately $6.0 million, and expenses of approximately $2.6 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates. Jefferies LLC and Cowen and Company, LLC acted as lead book-running managers. Wells Fargo Securities, LLC and William Blair & Company, L.L.C. acted as joint book-running manager for the IPO.

Shares of our common stock began trading on The Nasdaq Global Select Market on June 21, 2018. The offer and sale of the shares were registered under the Securities Act on a Registration Statement on Form S-1 (Registration No. 333-225194), which was declared effective on June 20, 2018.

There has been no material change in the planned use of proceeds from our IPO as described in our Prospectus. We invested the funds received in cash equivalents and other marketable securities in accordance with our investment policy. As of December 31, 2018, we have used approximately $10.5 million of the net offering proceeds primarily to advance our product candidates through clinical trial programs and for working capital and general corporate purposes.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Selected Financial Data.

You should read the following selected financial data together with the "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this report and our financial statements and the accompanying notes included elsewhere in this report. We have derived the statements of operations data for the years ended December 31, 2018, 2017 and 2016 and the balance sheet data as of December 31, 2018 and 2017 from our audited financial statements appearing elsewhere in this report. We have derived the balance sheet data as of December 31, 2016 from our audited financial statements not included in this report. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,		
(in thousands, except for share and per share data)	2018	2017	2016
Summary of Operations Data:			
Operating expenses:			
Research and development	$ 18,136	$ 6,469	$ 7,373
General and administrative	6,590	2,280	1,617
Total operating expenses	24,726	8,749	8,990
Loss from operations	(24,726)	(8,749)	(8,990)
Interest income	1,559	232	—
Net loss	$ (23,167)	$ (8,517)	$ (8,990)
Net loss per common share, basic and diluted	$ (2.26)	$ (14.21)	$ (26.56)
Weighted-average shares used to compute net loss per common share, basic and diluted (1)	10,264,584	599,291	338,446

(1) See Notes 2, 11 and 12 to our audited consolidated financial statements included elsewhere in this report for an explanation of the calculations of our basic and diluted net loss per share and the weighted-average number of shares used in the computation of the per share amounts.

	As of December 31,		
(in thousands)	2018	2017	2016
Selected Balance Sheet Data:			
Cash and cash equivalents	$ 24,182	$ 51,033	$ 9,747
Working capital	106,468	50,842	9,836
Total assets	114,682	54,222	11,424
Accumulated deficit	(49,195)	(26,028)	(17,511)
Total stockholders' equity (deficit)	108,797	(25,687)	(17,428)

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

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in "Special Note Regarding Forward-Looking Statements" and "Risk Factors."

Overview

We are a clinical-stage biotechnology company, discovering and developing novel small molecule therapeutics to treat unmet needs in autoimmunity and cancer. Our lead product candidate, KZR-616, a first-in-class selective immunoproteasome inhibitor, has completed testing in healthy volunteers and is now enrolling a Phase 1b/2 clinical trial in lupus and lupus nephritis. We believe that the immunoproteasome is a validated target for the treatment of a wide variety of autoimmune diseases, given the compelling published activity seen with proteasome inhibitors administered to patients with severe autoimmune diseases. Our Phase 1a clinical trial results provide evidence that KZR-616 avoids the side effects caused by non-selective proteasome inhibitors, side effects that prevent them from being developed as a treatment in autoimmunity. Initial top-line results from the Phase 1b portion of our trial are expected in the second quarter of 2019. In January 2019, we began enrolling healthy female patients in a Phase 1 trial, and we plan to initiate Phase 2 trials in up to four additional autoimmune indications in 2019. We are also leveraging our protein secretion pathway research platform to discover and develop small molecule therapies targeting cancer including immuno-oncology.

Since the commencement of our operations in mid-2015, we have devoted substantially all our resources to performing research and development activities in support of our product development efforts, hiring personnel, raising capital to support and expand such activities and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily from the issuance and sale of convertible preferred stock and from our initial public offering as described below.

On June 8, 2018, we effected a 1-for-5.62 reverse stock split of our issued and outstanding shares of common stock and redeemable convertible preferred stock. Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split.

On June 25, 2018, we completed our initial public offering, or IPO, whereby we sold 5,750,000 shares of our common stock, which included 750,000 shares issued as a result of the underwriters exercising their over-allotment option in full. We received cash proceeds of approximately $77.7 million from the IPO, net of underwriting discounts and commissions and other offering expenses paid by us.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates and programs. Our net losses were $23.2 million and $8.5 million for the years ended December 31, 2018 and 2017, respectively, and we expect to continue to incur significant losses for the foreseeable future. As of December 31, 2018, we had an accumulated deficit of $49.2 million. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on discovering, completing the necessary development, obtaining regulatory approval and preparing for potential commercialization of our product candidates.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical trials and expenditures on other research and development activities. We expect our expenses will increase substantially over time as we:

- continue the ongoing and planned development of KZR-616;

- seek to discover and develop additional product candidates;
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- establish a sales, marketing, manufacturing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- continue to build a portfolio of product candidates through the acquisition or in-license of drugs, product candidates or technologies;
- seek marketing approvals for KZR-616 and any future product candidates that successfully complete clinical trials;
- maintain, protect and expand our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- implement operational, financial and management systems; and
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel.

Critical Accounting Polices and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported 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.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued Research and Development Costs

We record accrued expenses for estimated costs of our research and development activities conducted by third-party service providers, which include the conduct of clinical studies, contract manufacturing activities and preclinical studies. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in accrued liabilities in the consolidated balance sheets and within research and development expense in the consolidated statements of operations. These costs are a significant component of our research and development expenses. We record accrued expenses for these costs based on factors such as estimates of the work completed and in accordance with agreements established with these third-party service providers. Any payments made in advance of services provided are recorded as prepaid assets, which are expensed as the contracted services are performed.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed, the number of patients enrolled and the rate of patient enrollment may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service

providers. For the periods presented, we have experienced no material differences between our accrued expenses and actual expenses.

Stock-Based Compensation

We recognize compensation costs related to stock options granted to employees and directors based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is recognized on a straight-line basis over the requisite service periods, which are generally the vesting period of the respective awards.

The Black-Scholes option-pricing model requires the use of subjective assumptions which determine the fair value of stock-based awards, including the expected term and the price volatility of the underlying stock. These assumptions include:

- *Expected term*—The expected term represents the period that the stock-based awards are expected to be outstanding. We used the simplified method, which calculates the expected term as the average of the time to vesting and the contractual life of the options. For non-employees, we use the contractual term.
- *Expected volatility*— The expected volatility was estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants as we do not have significant trading history for our common stock. The comparable companies were chosen based on their size, stage in the life cycle or area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.
- *Expected dividend*—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

We will continue to use judgment in evaluating the expected term and expected volatility utilized for our stock-based compensation calculations on a prospective basis.

Historically, for all periods prior to our IPO, the fair value of the shares of common stock underlying our share-based awards were estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, timely valuations of our common stock prepared by unrelated third-party valuation firms in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, and a number of objective and subjective factors including important developments in our operations, sales of convertible preferred stock, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of our common stock, among other factors. For the options granted subsequent to our June 2018 IPO, our board of directors will determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

Recent Accounting Pronouncements

See Note 2 to our Consolidated Financial Statements “Summary of Significant Accounting Policies—Recently Accounting Pronouncements” for more information.

Financial Operations Overview

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- fees paid to consultants for services directly related to our product development and regulatory effort;
- expenses incurred under agreements with third-party contract organizations, investigative clinical trial sites and consultants that conduct research and development activities on our behalf;
- costs associated with preclinical studies and clinical trials;
- costs associated with technology and intellectual property licenses;
- the costs related to production of clinical supplies; and
- facilities and other allocated expenses, which include expenses for rent and other facility related costs and other supplies.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, collaborators and third-party service providers.

We are eligible under the AusIndustry Research and Tax Development Tax Incentive Program to obtain a cash amount from the Australian Taxation Office. The tax incentive is available to us on the basis of specific criteria with which we must comply related to research and development expenditures in Australia. These research and development tax incentives are recognized as contra research and development expense when the right to receive has been attained and funds are considered to be collectible. The amounts are determined based on a cost-reimbursement basis, and the incentive is related to our research and development expenditures and is due to us regardless of whether any Australian tax is owed. Amounts related to the AusIndustry Research and Development Tax Incentive Program are recognized when there is reasonable assurance that the incentive will be received, the relevant expenditure has been incurred by our Australian subsidiary, Kezar Life Sciences Australia Pty Ltd, a proprietary company limited by shares, and the amount of the consideration can be reliably measured.

The following table summarizes our research and development expenses for the years ended:

	Year ended December 31,		
	2018	2017	2016
(dollars in thousands)		(unaudited)	
Research and development expenses by program:			
KZR-616	$ 12,665	$ 3,993	$ 5,542
Protein Secretion	5,471	2,476	1,831
Total research and development expenses	$ 18,136	$ 6,469	$ 7,373

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidate and our preclinical programs and as they advance into later stages of development. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs, allocated facilities costs and other expenses for outside professional services, including legal, human resource, IT and audit services. Personnel costs consist of salaries, benefits and stock-based compensation. We expect to incur additional expenses as a result of

operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, The Nasdaq Stock Market LLC and any other securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase the size of our administrative function to support the growth of our business.

Interest Income

Our interest income consists of interest income earned on our cash and cash equivalents and marketable securities.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

(dollars in thousands)	Year Ended December 31, 2018	2017	Change
Operating expenses:			
Research and development	$ 18,136	$ 6,469	$ 11,667
General and administrative	6,590	2,280	4,310
Total operating expenses	24,726	8,749	15,977
Loss from operations	(24,726)	(8,749)	(15,977)
Interest income	1,559	232	1,327
Net loss	$ (23,167)	$ (8,517)	$ (14,650)

Research and Development Expenses

Research and development expenses increased by $11.7 million in 2018 compared to 2017. The increase was due to an increase of $2.7 million in toxicology and other preclinical studies, an increase of $1.8 million in clinical trial costs for the Phase 1b clinical trial of KZR-616, an increase of $1.4 million related to manufacturing, an increase of $1.0 million in medicinal chemistry efforts related to our protein secretion discovery program, an increase of $0.8 million in stock-based compensation, an increase of $1.7 million in personnel expenses due to an increase in headcount and an increase of $1.8 million in facility-related expense due to the move to our new corporate office. In addition, the Australian Research and Development Tax Incentive credit earned for the year ended December 31, 2018 decreased by $0.5 million compared to the same period in 2017, which is recorded as a reduction in our research and development expenses.

General and Administrative Expenses

General and administrative expenses increased by $4.3 million in 2018 compared to 2017. The increase was primarily due to an increase of $1.1 million in stock-based compensation, an increase of $1.0 million in personnel expenses related to an increase in headcount and increased salaries, an increase of $1.8 million in consulting and professional fees related to being a public company and an increase of $0.4 million in facility-related expenses due to the move to our new corporate office.

Interest Income

Interest income increased by $1.3 million in 2018 compared to 2017. The increase was attributable to interest income earned on higher balances of cash equivalents and marketable securities resulting from our IPO in June 2018.

Comparison of the Years Ended December 31, 2017 and 2016

(dollars in thousands)	Year Ended December 31, 2017	2016	Change
Operating expenses:			
Research and development	$ 6,469	$ 7,373	$ (904)
General and administrative	2,280	1,617	663
Total operating expenses	8,749	8,990	(241)
Loss from operations	(8,749)	(8,990)	241
Interest income	232	—	232
Net loss	$ (8,517)	$ (8,990)	$ 473

Research and Development Expenses

Research and development expenses decreased by $0.9 million for the year ended December 31, 2017, compared to the year ended December 31, 2016. The decrease was due to a reduction of $1.9 million in the costs of GLP toxicology studies, which were mostly completed in 2016, and a reduction of $0.5 million in contract manufacturing related process development costs. These decreases were partially offset by an increase of $0.9 million in clinical trial costs due to the initiation of the Phase 1 clinical trial of KZR-616, an increase of $0.5 million in personnel expenses due to an increase in headcount and an increase of $0.3 million in medicinal chemistry efforts related to our protein secretion discovery program. In addition, the amount of our Australian Research and Development Tax Incentive increased by $0.1 million for the year ended December 31, 2017.

General and Administrative Expenses

General and administrative expenses increased by $0.7 million for the year ended December 31, 2017, compared to the year ended December 31, 2016. The increase was primarily due to an increase of $0.3 million in payroll expenses related to an increase in headcount and increased salaries and bonuses and an increase of $0.2 million in legal and professional fees related to our intellectual property activities and preparation to become a public company.

Interest Income

Interest income increased by $0.2 million for the year ended December 31, 2017, compared to the year ended December 31, 2016. The increase was attributable to interest income earned on cash equivalents due to additional funds received from our Series B redeemable convertible preferred stock financing in June and July 2017.

Liquidity and Capital Resources

Overview

As of December 31, 2018, we had $24.2 million in cash and cash equivalents and $83.3 million of marketable securities invested in a U.S. Treasury money market fund, U.S. Treasury securities, U.S. Agency bonds and corporate debt securities with maturities of eight months or less.

In June 2018, we completed an IPO whereby we sold 5,750,000 shares of our common stock at a price of $15.00 per share, which included 750,000 shares as a result of the underwriters exercising their over-allotment option exercised in full. We received net proceeds of $77.7 million from the IPO, after deducting underwriting discounts and commissions and other offering expenses paid by us. Prior to the IPO, we raised an aggregate of $72.6 million from the sale of convertible preferred stock, which automatically converted to common stock on a one-for-one ratio upon completion of the IPO.

We have incurred operating losses and experienced negative operating cash flows since our inception and anticipate that we will continue to incur losses for at least the foreseeable future. Our net loss was $23.2 million for the year ended December 31, 2018, and we had an accumulated deficit of $49.2 million as of December 31, 2018.

We believe that our cash, cash equivalents and marketable securities as of December 31, 2018 will be sufficient to meet our projected operating requirements through at least the next 12 months from the date these financial statements are issued. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Funding Requirements

Our primary use of cash is to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

We will require additional financing to fund working capital and pay our obligations. We may pursue financing opportunities through the issuance of debt or equity. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us or at all. Our future funding requirements will depend on many factors, including the following:

- the progress, timing, scope, results and costs of our clinical trials and preclinical studies for our product candidates, including the ability to enroll patients in a timely manner for our clinical trials;
- the costs of obtaining clinical and commercial supplies for KZR-616 and any other product candidates we may identify and develop;
- the cost, timing and outcomes of regulatory approvals;
- the extent to which we may acquire or in-license other product candidates and technologies;
- the cost of attracting, hiring and retaining qualified personnel;
- our ability to successfully commercialize any product candidates for which we obtain regulatory approval; and
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

If we need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies, clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations and other licensing arrangements. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Cash Flows

The following summarizes our cash flows for the periods indicated:

	Year Ended December 31,		
	2018	2017	2016
(dollars in thousands)			
Cash used in operating activities	$ (20,792)	$ (8,109)	$ (9,760)
Cash used in investing activities	(83,904)	(389)	(132)
Cash provided by financing activities	77,913	49,755	36
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(81)	29	(150)
Net (decrease) increase in cash and cash equivalents and restricted cash	$ (26,864)	$ 41,286	$ (10,006)

Cash Flows from Operating Activities

During the year ended December 31, 2018, cash used in operating activities was $20.8 million, which consisted of a net loss of $23.2 million, adjusted by non-cash charges of $2.3 million and a net change of $0.1 million in our net operating assets and liabilities. The non-cash charges consisted of $0.2 million for depreciation and amortization, $2.0 million for stock-based compensation expense and $0.1 million for loss on disposal of property and equipment. The change in our net operating assets and liabilities was primarily due to an increase of $1.0 million in prepaid expenses, including upfront payments for insurance premiums, clinical and toxicology activities, offset by an increase of $1.4 million in accounts payable, accrued expenses and other liabilities due to professional services, manufacturing and clinical expenditures as well as an increase of $0.3 million related to deferred rent.

During the year ended December 31, 2017, cash used in operating activities was $8.1 million, which consisted of a net loss of $8.5 million, adjusted by non-cash charges of $0.4 million. The non-cash charges are primarily comprised of $0.2 million for depreciation and amortization and of $0.2 million for stock-based compensation expense. The change in our net operating assets and liabilities was primarily due to an increase in payroll-related accruals of $0.4 million and clinical expenditures of $0.3 million and an increase in prepaid expenses of $0.6 million, including advance payments for clinical activities.

During the year ended December 31, 2016, cash used in operating activities was $9.8 million, which consisted of a net loss of $9.0 million, adjusted by non-cash charges of $0.3 million and a net change of $1.1 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of $0.2 million for depreciation and amortization and $0.1 million for stock-based compensation expense. The change in our net operating assets and liabilities was primarily due to a decrease of $0.5 million in accounts payable primarily related to clinical development expenditures and an increase of $0.4 million for research and development tax incentive receivable.

Cash Flows from Investing Activities

During the year ended December 31, 2018, cash used in investing activities primarily consisted of $119.2 million in purchases of marketable securities offset by $36.5 million of maturities of such marketable securities. Purchases of property and equipment was $1.1 million, $0.4 million and $0.1 million during the years ended December 31, 2018, 2017 and 2016, respectively.

Cash Flows from Financing Activities

During the year ended December 31, 2018, cash provided by financing activities was $77.9 million, which consisted of $77.7 million in net proceeds from our IPO and $0.2 million from the issuance of common stock upon the exercise of stock options.

During the year ended December 31, 2017, cash provided by financing activities consisted of $49.8 million in net proceeds from the issuance of Series B redeemable convertible preferred stock. During the year ended December 31,

2016, cash provided by financing activities consisted of $36,000 in net proceeds from the issuance of common stock upon the exercise of stock options.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of December 31, 2018 (in thousands):

CONTRACTUAL OBLIGATIONS	TOTAL	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating leases (1)	$ 9,681	$ 1,453	$ 3,038	$ 3,223	$ 1,967
Total obligations	$ 9,681	$ 1,453	$ 3,038	$ 3,223	$ 1,967

(1) Amounts in the table represent the operating lease obligations of office and laboratory space at 4000 Shoreline Court, South San Francisco, California. The minimum lease payments above do not include common area maintenance charges or real estate taxes.

Except as disclosed in the table above, we have no long-term debt or capital leases and no material non-cancelable purchase commitments with service providers, as we have generally contracted on a cancelable, purchase order basis.

The contractual obligations table does not include any potential contingent payments upon the achievement by us of clinical, regulatory and commercial events, as applicable, or royalty payments that we may be required to make under license agreements we have entered into or may enter into with various entities pursuant to which we have in-licensed certain intellectual property, including our license agreement with Onyx. Under the Onyx license agreement, we are obligated to pay Onyx milestone payments of up to $172.5 million in the aggregate upon the achievement of certain development, regulatory and sales milestones. We excluded the contingent payments given that the timing and amount (if any) of any such payments cannot be reasonably estimated at this time. See the section titled “Business—License Agreement with Onyx” for additional information.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have holdings in any variable interest entities.

JOBS Act Accounting Election

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. 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.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an “emerging growth company” we intend to rely on such exemptions, we are not required to, among other things, (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis) and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation. These exemptions will apply until December 31, 2023 or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

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

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. The market risk inherent in our financial instruments and in our financial position reflects the potential losses arising from adverse changes in interest rates and concentration of credit risk. We had cash, cash equivalents and marketable securities of $107.4 million as of December 31, 2018, which consisted of bank deposits, highly liquid money market funds, U.S. Treasury securities, U.S. Agency bonds and corporate debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of December 31, 2018, our cash equivalents and marketable securities had maturities of six months or less. Due to the short-term duration and the lower risk profile of our cash equivalents and marketable securities, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities. We have the ability to hold our cash equivalents and marketable securities until maturity, and we therefore do not expect a change in market interest rates to affect our operating results or cash flows to any significant degree.

Approximately $1.0 million of our cash balance is denominated in Australian dollars and deposited in an Australian bank as of December 31, 2018. Our expenses, except those related to our Australian operations, are generally denominated in U.S. dollars. For our operations in Australia, the majority of the expenses are denominated in Australian dollars. To date, we have not had a formal hedging program with respect to foreign currency. A 10% increase or decrease in current exchange rates would not have a material effect on our consolidated financial results.

Item 8. Financial Statements and Supplementary Data.

The financial statements required by this item are set forth beginning on page F-1 of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Material Weakness in Our Internal Control Over Financial Reporting

In connection with the audit of our consolidated financial statements as of and for the years ended December 31, 2016 and 2017, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. The material weakness was related to a lack of sufficient number of qualified personnel within our accounting function to adequately segregate duties, a lack of sufficient review and approval of manual journal entries posted to the general ledger and a lack of adequate review procedures over general ledger account reconciliations.

This control deficiency did not result in a material misstatement of our current or prior period consolidated annual or interim financial statements. However, this control deficiency could have resulted in material misstatements to the annual or interim consolidated financial statements that would not have been prevented or detected. Accordingly, management concluded that this control deficiency constituted a material weakness.

Remediation of Material Weakness

During the year ended December 31, 2018, we implemented measures designed to enhance our internal control over financial reporting to remediate this material weakness, including the following:

- we have added additional qualified accounting personnel, including our Chief Financial Officer and controller, and ensured proper segregation of duties among accounting personnel; and
- we have formalized our documentation with our existing financial processes, risk assessment and internal controls, and strengthened supervisory reviews by our management.

These additional resources and procedures are designed to enable us to broaden the scope and quality of our internal review of underlying information related to financial reporting and to formalize and enhance our internal control procedures. As of December 31, 2018, we were able to demonstrate that these measures implemented as part of our remediation efforts were operating effectively, and management therefore concluded that the material weakness described above has been remediated as of that date.

Evaluation of Disclosure Controls and Procedures.

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, 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.

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018. Based on the evaluation of our disclosure controls and procedures as of December 31, 2018, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting.

Due to a transition period established by SEC rules applicable to newly public companies, our management is not required to evaluate the effectiveness of our internal control over financial reporting until after the filing of our Annual Report on Form 10-K for the year ended December 31, 2018.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption for "emerging growth companies."

Changes in Internal Control over Financial Reporting.

Other than described in "Remediation of Material Weakness" above, there were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter 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 by this item is incorporated by reference to the information set forth in the sections titled “Information About Our Board of Directors” and “Information About Our Executive Officers Who Are Not Directors,” “Corporate Governance,” “Corporate Governance – Code of Business Conduct and Ethics,” “Section 16(a) Beneficial Ownership Reporting Compliance,” “Corporate Governance – Committees of the Board of Directors – Nominating and Corporate Governance Committee,” “Corporate Governance – Committees of the Board of Directors – Audit Committee” and “Corporate Governance – Committees of the Board of Directors – Compensation Committee” in our Proxy Statement.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the information set forth in the sections titled “Executive Compensation,” “Director Compensation” and “Committees of the Board of Directors — Compensation Committee Interlocks and Insider Participation” in our Proxy Statement.

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

The information required by this item is incorporated by reference to the information set forth in the sections titled “Securities Authorized For Issuance Under Equity Compensation Plans” and “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement.

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

The information required by this item is incorporated by reference to the information set forth in the sections titled “Corporate Governance – Board of Directors Independence” and “Transactions With Related Persons” in our Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to the information set forth in the sections titled “Independent Registered Public Accounting Firm Fees and Services” in our Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

The financial statements schedules and exhibits filed as part of this Annual Report on Form 10-K are as follows:

(a)(1) Financial Statements

Reference is made to the financial statements included in Item 8 of Part II hereof.

(a)(2) Financial Statement Schedules

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

(a)(3) Exhibits

The exhibits required to be filed as part of this report are listed in the Exhibit List attached hereto and are incorporated herein by reference.

Item 16. Form 10-K Summary

None.

Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38542), filed with the Commission on June 26, 2018).
3.2	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38542), filed with the Commission on June 26, 2018).
4.1	Form of Common Stock Certificate of the Company (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-225194), filed with the Commission on June 8, 2018).
4.2	Amended and Restated Investors' Rights Agreement, by and among the Company and certain of its stockholders, dated June 26, 2017 (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
10.1+	Form of Indemnity Agreement by and between the Company and its directors and officers (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
10.2+	2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-8 (File No. 333-225769), filed with the Commission on June 21, 2018).
10.3+	Forms of Option Grant Notice and Option Agreement under 2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
10.4+	Form of Restricted Stock Unit Grant Notice and Unit Award Agreement under 2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
10.5+	2015 Equity Incentive Plan, as amended (incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
10.6+	Form of Stock Option Agreement under the 2015 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
10.7+	Form of Stock Option Agreement—Early Exercise under the 2015 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
10.8+	2018 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 4.12 to the Company's Registration Statement on Form S-8 (File No. 333-225769), filed with the Commission on June 21, 2018).
10.9+	Amended and Restated Executive Employment Agreement between the Company and John Fowler, dated June 7, 2018 (incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1/A (File No. 333-225194), filed with the Commission on June 8, 2018).
10.10+	Amended and Restated Executive Employment Agreement between the Company and Christopher J. Kirk, dated June 7, 2018 (incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1/A (File No. 333-225194), filed with the Commission on June 8, 2018).
10.11†	Exclusive License Agreement by and between the Company and Onyx Therapeutics, Inc., dated June 11, 2015 (incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A (File No. 333-225194), filed with the Commission on June 8, 2018).
10.12	Lease between the Company and AP3-SF1 4000 Shoreline, LLC, dated August 16, 2017 (incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).

10.13	Confirmation of Lease Terms between the Company and AP3-SF1 4000 Shoreline, LLC, effective as of March 1, 2018.
21.1	Subsidiaries of the Company (incorporated herein by reference to Exhibit 21.1 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page to this report).
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 and 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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* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

\+ Indicates a management contract or compensatory plan.

† Confidential treatment has been granted for certain portions of this exhibit. These portions have been omitted and filed separately with the SEC.

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**.**

Kezar Life Sciences, Inc.
(Registrant)

March 26, 2019

By: /s/ John Fowler
John Fowler
Chief Executive Officer
(Principal Executive Officer)

March 26, 2019

By: /s/ Marc L. Belsky
Marc L. Belsky
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints John Fowler and Marc L. Belsky, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report on Form 10-K 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/ John Fowler **John Fowler**	Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2019
/s/ Marc L. Belsky **Marc L. Belsky**	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 26, 2019
/s/ John-Pierre Sommadossi, Ph.D. **John-Pierre Sommadossi, Ph.D**	Chairman of the Board of Directors	March 26, 2019
/s/ Franklin M. Berger, CFA **Franklin M. Berger, CFA**	Director	March 26, 2019
/s/ Graham Cooper **Graham Cooper**	Director	March 26, 2019
/s/ Jason Dinges, Ph.D., J.D. **Jason Dinges, Ph.D., J.D.**	Director	March 26, 2019
/s/ Michael Kauffman, M.D., Ph.D. **Michael Kauffman, M.D., Ph.D.**	Director	March 26, 2019
/s/ Christopher Kirk, Ph.D. **Christopher Kirk, Ph.D.**	President, Chief Scientific Officer and Director	March 26, 2019

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Kezar Life Sciences, Inc.:

Opinion on the Consolidated Financial Statements
We have audited the accompanying consolidated balance sheets of Kezar Life Sciences, Inc. and subsidiary (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion
These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

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

San Francisco, California
March 26, 2019

KEZAR LIFE SCIENCES, INC.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 24,182	$ 51,033
Marketable securities	83,250	—
Prepaid expenses	1,884	785
Other current assets	489	508
Total current assets	109,805	52,326
Restricted cash	—	13
Property and equipment, net	4,595	1,540
Other assets	282	343
Total assets	$ 114,682	$ 54,222
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 193	$ 547
Accrued liabilities	2,678	911
Deferred rent, current	354	—
Other liabilities, current	112	26
Total current liabilities	3,337	1,484
Deferred rent, noncurrent	2,548	494
Total liabilities	5,885	1,978
Redeemable convertible preferred stock, $0.001 par value, zero and 75,533,240 shares authorized as of December 31, 2018 and 2017, respectively; zero and 12,263,126 shares issued and outstanding as of December 31, 2018 and 2017, respectively	—	77,931
Stockholders' equity (deficit):		
Common stock, $0.001 par value, 125,000,000 and 96,000,000 shares authorized as of December 31, 2018 and 2017, respectively; 19,114,421 and 948,578 shares issued and outstanding as of December 31, 2018 and 2017, respectively	19	1
Preferred stock, $0.001 par value, 10,000,000 and zero shares authorized as of December 31, 2018 and 2017, respectively; zero shares issued and outstanding as of December 31, 2018 and 2017	—	—
Additional paid-in capital	158,176	451
Accumulated other comprehensive loss	(203)	(111)
Accumulated deficit	(49,195)	(26,028)
Total stockholders' equity (deficit)	108,797	(25,687)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 114,682	$ 54,222

The accompanying notes are an integral part of these consolidated financial statements.

KEZAR LIFE SCIENCES, INC.
Consolidated Statements of Operations
(In thousands except share and per share data)

	Year Ended December 31,		
	2018	**2017**	**2016**
Operating expenses:			
Research and development	$ 18,136	$ 6,469	$ 7,373
General and administrative	6,590	2,280	1,617
Total operating expenses	24,726	8,749	8,990
Loss from operations	(24,726)	(8,749)	(8,990)
Interest income	1,559	232	—
Net loss	$ (23,167)	$ (8,517)	$ (8,990)
Net loss per common share, basic and diluted	$ (2.26)	$ (14.21)	$ (26.56)
Weighted-average shares used to compute net loss per common share, basic and diluted	10,264,584	599,291	338,446

The accompanying notes are an integral part of these consolidated financial statements.

KEZAR LIFE SCIENCES, INC.
Consolidated Statements of Comprehensive Loss
(In thousands)

	Year Ended December 31,		
	2018	2017	2016
Net loss	$ (23,167)	$ (8,517)	$ (8,990)
Other comprehensive (loss) income, net of tax:			
Foreign currency translation adjustments	(72)	39	(150)
Unrealized loss on marketable securities	(20)	—	—
Total other comprehensive (loss) income, net of tax	(92)	39	(150)
Comprehensive loss	$ (23,259)	$ (8,478)	$ (9,140)

See accompanying notes to the consolidated financial statements

KEZAR LIFE SCIENCES, INC.

Consolidated Statement of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

(In thousands, except share and per share amounts)

	REDEEMABLE CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED OTHER COMPREHENSIVE	ACCUMULATED	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNTS	SHARES	AMOUNTS	CAPITAL	INCOME (LOSS)	DEFICIT	(DEFICIT)
Balance at December 31, 2015	5,966,753	$ 28,176	911,151	$ 1	$ 104	$ —	$ (8,521)	$ (8,416)
Issuance of common stock upon exercise of stock options, net of amount related to early exercised options	—	—	37,427	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	128	—	—	128
Other comprehensive loss	—	—	—	—	—	(150)	—	(150)
Net loss	—	—	—	—	—	—	(8,990)	(8,990)
Balance at December 31, 2016	5,966,753	28,176	948,578	1	232	(150)	(17,511)	(17,428)
Issuance of Series B redeemable convertible preferred stock for cash of $7.942 per share, net of $245 issuance costs	6,296,373	49,755	—	—	—	—	—	—
Vesting related to common shares issued pursuant to early exercises	—	—	—	—	16	—	—	16
Stock-based compensation expense	—	—	—	—	203	—	—	203
Other comprehensive loss	—	—	—	—	—	39	—	39
Net loss	—	—	—	—	—	—	(8,517)	(8,517)
Balance at December 31, 2017	12,263,126	77,931	948,578	1	451	(111)	(26,028)	(25,687)
Conversion of redeemable convertible preferred stock to common stock	(12,263,126)	(77,931)	12,263,126	12	77,919	—	—	77,931
Issuance of common stock upon initial public offering, net of issuance costs	—	—	5,750,000	6	77,689	—	—	77,695
Issuance of common stock upon exercise of stock options, net of amount related to early exercised options	—	—	142,528	—	55	—	—	55
Issuance of common stock upon vesting of restricted stock units	—	—	10,189	—	—	—	—	—
Vesting related to common shares issued pursuant to early exercises	—	—	—	—	69	—	—	69
Stock-based compensation expense	—	—	—	—	1,993	—	—	1,993
Other comprehensive loss	—	—	—	—	—	(92)	—	(92)
Net loss	—	—	—	—	—	—	$ (23,167)	(23,167)
Balance at December 31, 2018	—	$ —	19,114,421	$ 19	$ 158,176	$ (203)	$ (49,195)	$ 108,797

The accompanying notes are an integral part of these consolidated financial statements.

KEZAR LIFE SCIENCES, INC.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net loss	$ (23,167)	$ (8,517)	$ (8,990)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	690	175	154
Stock-based compensation	1,993	203	128
Amortization of premiums and discounts on marketable securities	(476)	—	—
Loss on disposal of property and equipment	106	—	—
Changes in operating assets and liabilities			
Prepaid expenses & other current assets	(1,136)	(543)	(598)
Other assets	61	(282)	—
Accounts payable & accrued liabilities	1,440	844	(469)
Other liabilities, current	(8)	6	—
Deferred rent	(295)	5	15
Net cash used in operating activities	(20,792)	(8,109)	(9,760)
Cash flows from investing activities:			
Purchases of property and equipment	(1,120)	(389)	(132)
Purchases of marketable securities	(119,244)	—	—
Maturities of marketable securities	36,450	—	—
Proceeds from sale of property and equipment	10	—	—
Net cash used in investing activities	(83,904)	(389)	(132)
Cash flows from financing activities:			
Proceeds from initial public offering, net of issuance costs	77,695	—	—
Proceeds from issuance of preferred stock, net of issuance costs	—	49,755	—
Proceeds from the exercise of stock options	218	—	36
Net cash provided by financing activities	77,913	49,755	36
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(81)	29	(150)
Net (decrease) increase in cash, cash equivalents and restricted cash	(26,864)	41,286	(10,006)
Cash, cash equivalents and restricted cash at the beginning of period	51,046	9,760	19,766
Cash, cash equivalents and restricted cash at the end of period	$ 24,182	$ 51,046	$ 9,760
Supplemental disclosures of noncash financing information:			
Reclassification of employee stock liability to equity upon vesting	$ 69	$ 16	$ —
Addition of tenant improvement paid by landlord	$ 2,703	$ 464	$ —
Purchase of property and equipment in accounts payable	$ 38	$ —	$ —
Conversion of redeemable convertible preferred stock into common stock	$ 77,931	$ —	$ —

The accompanying notes are an integral part of these consolidated financial statements.

1. Organization and Description of the Business

Description of Business

Kezar Life Sciences, Inc. (the "Company") was incorporated in Delaware on February 19, 2015, and commenced operations in June 2015. The Company is a clinical-stage biotechnology company, discovering and developing novel small molecule therapeutics to treat unmet needs in autoimmunity and cancer. The Company's principal operations are in South San Francisco, California, and it operates in one segment.

Reverse Stock Split

On June 8, 2018, the Company filed an Amended and Restated Certificate of Incorporation effecting a 1-for-5.62 reverse stock split of its issued and outstanding shares of common stock and redeemable convertible preferred stock. The par value of the authorized stock was not adjusted as a result of the reverse stock split. In connection with the reverse stock split, the filed Amended and Restated Certificate of Incorporation also adjusted the minimum price per share required in a firm-commitment underwritten public offering of the Company's common stock in order for the preferred stock to automatically convert to common stock. The minimum price post-split was $15.884 and was adjusted to $7.942. The Company did not adjust the number of authorized shares of common stock or redeemable convertible preferred stock. Other than the par value and the number of authorized shares of common stock and preferred stock, all share and per share data shown in the accompanying consolidated financial statements and related notes have been retroactively revised to reflect the reverse stock split.

Initial Public Offering

On June 25, 2018, the Company completed its initial public offering ("IPO"), whereby the Company issued 5,750,000 shares of its common stock (inclusive of 750,000 shares of common stock pursuant to the full exercise of an overallotment option granted to the underwriters in connection with the offering) at a price of $15.00 per share. The shares began trading on The Nasdaq Global Select Market on June 21, 2018. The net proceeds received by the Company from the offering were approximately $77.7 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company of approximately $8.6 million. Upon the closing of the IPO, all outstanding shares of redeemable convertible preferred stock converted into 12,263,126 shares of common stock. Additionally, the Company is now authorized to issue 125,000,000 shares of common stock and 10,000,000 shares of preferred stock.

Liquidity

Since commencing operations in mid-2015, substantially all of the Company's efforts have been focused on research, development, and the advancement of the Company's lead product candidate, KZR-616. The Company's ultimate success depends on the outcome of the ongoing research and development activities. The Company has not yet generated product sales and as a result has experienced operating losses since inception and had an accumulated deficit of $49.2 million as of December 31, 2018. The Company expects to incur additional losses in the future to conduct research and development and will need to raise additional capital to fully implement management's business plan. The Company intends to raise such capital through the issuance of additional equity, and potentially through borrowings, strategic alliances with partner companies and other licensing transactions. However, if such financing is not available at adequate levels, the Company may need to reevaluate its operating plans. Management believes that its existing cash, cash equivalents and marketable securities will be sufficient to fund the Company's cash requirements for at least 12 months following the issuance of these financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") and include the Company's accounts and those of its wholly owned Australian subsidiary, Kezar Life Sciences Australia Pty Ltd, which is a proprietary company limited by shares. All intercompany balances and transactions have been eliminated upon consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant items subject to such estimates and assumptions include the useful lives of fixed assets, stock-based compensation, and accrued research and development costs. Management bases its estimates on historical experience and on various other market-specific relevant assumptions that management believes to be reasonable under the circumstances. Actual results may differ from those estimates.

Foreign Currency Translation

The functional currency of the Company's non-U.S. subsidiary is the Australian dollar. Asset and liability balances denominated in non-U.S. dollar currency are translated into U.S. dollars using period-end exchange rates, while expenses are based upon the exchange rate at the time of the transaction, if known, or at the average rate for the period. Equity accounts, except for the change in accumulated deficit during the year, have been translated using historical exchange rates. Differences are included in stockholders' equity as a component of accumulated other comprehensive loss.

Cash and Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents are stated at fair value.

Restricted cash consisted of deposits at the bank held as collateral for the Company's credit card program. The collateral requirement was removed and released in May 2018.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the consolidated statements of cash flows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Cash and cash equivalents	$ 24,182	$ 51,033	$ 9,747
Restricted cash	—	13	13
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	$ 24,182	$ 51,046	$ 9,760

Marketable Securities

All marketable securities have been classified as "available-for-sale" and are carried at fair value, based upon quoted market prices. The Company considers its available-for-sale portfolio as available for use in current operations. Unrealized gains and losses, net of any related tax effects, are excluded form earnings and are included in other comprehensive income or loss and reported as a separate component of stockholders' equity or deficit until realized. Realized gains and losses and declines in value judged to be other than temporary, if any, on available-for-sale securities are included in other income (expense), net. The cost of securities sold is based on the specific-

identification method. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion, together with interest on securities, are included in interest income on the Company's consolidated statements of operations. In accordance with the Company's investment policy, management invests to diversify credit risk and only invests in debt securities with high credit quality, including U.S. government securities.

The Company regularly reviews all of its investments for other-than-temporary declines in estimated fair value. Its review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that the Company will be required to sell the securities before the recovery of their amortized cost basis. When the Company determines that the decline in estimated fair value of an investment is below the amortized cost basis and the decline is other-than-temporary, it reduces the carrying value of the security and record a loss for the amount of such decline. The Company has not recorded any realized losses or declines in value judged to be other than temporary on its investments in debt securities.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The majority of the Company's cash, cash equivalents and marketable securities are held by financial institutions in the United States, while approximately $1.0 million is held by a financial institution in Australia. Such deposits in the United States may be in excess of insured limits.

Impairment of Long-Lived Assets

Long-lived assets include property and equipment. The Company reviews the carrying value of long-lived assets for impairment whenever events or changes in circumstances indicate that the assets may not be recoverable. The Company recognizes an impairment loss when the total estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. Through December 31, 2018, there have been no such impairment losses.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation on property and equipment is calculated on the straight-line method over the estimated useful lives of the assets. Furniture, laboratory and office equipment are depreciated over five to seven years. Computer equipment are depreciated over three years. Leasehold improvements are amortized over the shorter of their estimated useful lives or the related lease term.

Other Assets

Other assets consist of security deposits for the Company's operating leases of office and laboratory space.

Fair Value of Financial Instruments

Financial assets and liabilities are recorded at fair value. The carrying amount of certain financial instruments, including cash, cash equivalents, marketable securities, other current assets, restricted cash, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities. Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

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

Level 2: Observable inputs other than Level 1 prices, 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 the assets or liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The Company applies fair value accounting for all financial assets and liabilities and nonfinancial assets and liabilities that are required to be recognized or disclosed at fair value in the financial statements. The Company determines the fair value of Level 1 assets using quoted prices in active markets for identical assets. The Company reviews trading activity and pricing for Level 2 investments as of each measurement date. Level 2 inputs, which are obtained from various third-party data providers, represent quoted prices for similar assets in active markets and were derived from observable market data, or, if not directly observable, were derived from or corroborated by other observable market data. There were no transfers between Level 1 and Level 2 securities in the periods presented.

In certain cases, where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3 within the valuation hierarchy. The Company does not have any assets or liabilities measured using Level 3 inputs as of December 31, 2018 and 2017.

The following table summarizes our financial assets measured at fair value on a recurring basis (in thousands):

	December 31, 2018			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 23,156	$ 23,156	$ —	$ —
U.S. Treasury securities	25,692	25,692	—	—
Commercial paper	19,190	—	19,190	—
Corporate debt securities	20,451	—	20,451	—
Government agency bonds	17,917	—	17,917	—
Total	$ 106,406	$ 48,848	$ 57,558	$ —

	December 31, 2017			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 50,242	$ 50,242	$ —	$ —
Total	$ 50,242	$ 50,242	$ —	$ —

Research and Development Costs

Research and development costs are expensed as incurred and consist primarily of salaries and benefits, stock-based compensation expense, lab supplies and facility costs, as well as fees paid to nonemployees and entities that conduct certain research and development activities on the Company's behalf and expenses incurred in connection with license agreements. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are capitalized and then expensed as the related goods are delivered or the services are performed.

The Company accrues for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical and clinical studies and contract manufacturing activities. The Company estimates the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. The Company makes significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, the Company adjusts the accrued estimates. Although the Company does not expect the estimates to be materially different from amounts actually incurred, the status and timing of services performed, the number of patients enrolled and the rate of patient enrollment may vary from the Company's estimates and could result in the Company reporting amounts that are too high or too low in any particular period. The Company's accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. To date, there have been no material differences from the Company's accrued expenses to actual expenses.

Research and Development Tax Incentive

The Company is eligible under the AusIndustry Research and Tax Development Tax Incentive Program to obtain a cash amount from the Australian Taxation Office (ATO). The tax incentive is available to the Company on the basis of specific criteria with which the Company must comply related to research and development expenditures in Australia. These research and development tax incentives are recognized as contra research and development expense when the right to receive has been attained and funds are considered to be collectible.

The Company recognized $5,000, $499,000 and $385,000 as a reduction of research and development expenses for the years ended December 31, 2018, 2017 and 2016, respectively, in connection with the research and development tax incentive from the ATO. As of December 31, 2018 and 2017, the research and development tax credit receivable was $5,000 and $498,000, respectively, which is included in other current assets in the consolidated balance sheets.

Stock-Based Compensation

Stock-based awards issued to employees and directors, including stock options, are recorded at fair value as of the grant date using the Black-Scholes option pricing model and recognized as expense on a straight line-basis over the employee's or director's requisite service period (generally the vesting period). The Company accounts for forfeitures as they occur by reversing any expense recognized for unvested awards.

Stock-based awards and stock options issued to nonemployee consultants are recorded at fair value as of the grant date using the Black-Scholes option pricing model. The unearned portion of the stock-based compensation is remeasured at each reporting period using the Black-Scholes option pricing model, and the resulting change in fair value is recognized in the statements of operations over the remaining period the related services are rendered.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

The Company records a valuation allowance against deferred tax assets if it is more likely than not that a portion or all of the asset will not be realized in future periods. In making such determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations.

The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on their technical merits, as the largest amount of benefit that is more likely than not to be realized upon the ultimate settlement. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest charges or penalties related to unrecognized tax benefits.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is the same as basic net loss per share for the periods presented since the effects of potentially dilutive securities are antidilutive given the net loss of the Company.

Accounting Pronouncements Adopted in 2018

In May 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2017-09, *Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting*. This ASU provides guidance about which changes to the terms or conditions of a share-based payment award requires the Company to apply modification accounting. This ASU will be effective for the Company for annual reporting periods, including interim reporting periods, beginning after December 15, 2017. The Company adopted this standard on January 1, 2018 noting it did not have a material impact on the Company's financial statements.

New Accounting Pronouncements Not Yet Adopted

Leases (Topic 842)

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. ASU 2016-02 increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and requires disclosing key information about leasing arrangements. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides entities the option to initially apply the transition provisions of ASU 2016-02 at its adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

The Company expects to adopt the new standard on January 1, 2019 and use the effective date as its date of initial application. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019.

The Company expects that this standard will have a material effect on its financial statements. While the Company continues to assess all of the effects of adoption, it currently believes the most significant effects relate to (1) the recognition of new right-of-use (ROU) assets and lease liabilities on its balance sheet for its operating lease for its headquarters at 4000 Shoreline Court, South San Francisco; and (2) providing significant new disclosures about its leasing activities.

On adoption, the Company currently expects to recognize an operating lease liability of approximately $7.1 million based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. The operating lease ROU asset of approximately $4.2 million consists of the amount of the initial measurement of lease liability, net of the unamortized lease incentives previously received of approximately $2.9 million that are currently recorded as deferred rent liabilities on its consolidated balance sheet.

The new standard also provides practical expedients for an entity's ongoing accounting. The Company currently expects to elect the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. The Company will not elect the practical expedient to not separate lease and non-lease components for all of its leases.

Other recent accounting announcements

In June 2016, FASB issued *ASU 2016-13, Financial Instruments-Credit Losses (Topic 326)*, or ASU 2016-13. ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. This guidance will become effective for us beginning in the first quarter of 2020 and must be adopted using a modified retrospective approach, with certain exceptions. Early adoption is permitted beginning in the first quarter of 2019. The Company is currently evaluating the potential impact of the adoption of this guidance on its financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718)*. ASU 2018-07 simplifies the accounting for nonemployee share-based payment transactions. This ASU is effective for public entities for interim and annual reporting periods beginning after December 15, 2018. The Company has evaluated the potential impact of this guidance and does not believe that it will have a material impact on the Company's financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements on fair value measurements. The amendment of ASU No. 2018-13 removes disclosure requirements from Topic 820 in the areas of (1) the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; (2) the policy for timing of transfers between levels, and (3) the valuation processes for Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the effect the new guidance will have on its consolidated financial statements.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, Disclosure Update and Simplification. Among the amendments is the requirement to present the changes in stockholders' equity in the interim financial statements included in quarterly reports on Form 10-Q. The amendments are effective for all filings made on or after November 5, 2018. However, registrants may begin providing the new interim reconciliations of stockholders' equity in the Form 10-Q for the interim period beginning after the effective date. The Company plans to implement the changes required by these amendments to its Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) in its Form 10-Q filing for the period ended March 31, 2019.

3. Cash Equivalents and Marketable Securities

As of December 31, 2018 and 2017, financial assets and liabilities measured and recognized at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above were as follows (in thousands):

	December 31, 2018			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Financial Assets:				
Money market funds	$ 23,156	$ —	$ —	$ 23,156
U.S. Treasury securities	25,698	—	(6)	25,692
Commercial paper	19,203	—	(13)	19,190
Corporate debt securities	20,449	4	(2)	20,451
Government agency bonds	17,921	—	(4)	17,917
Total	$ 106,427	$ 4	$ (25)	$ 106,406

	December 31, 2017			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Financial Assets:				
Money market funds	$ 50,242	$ —	$ —	$ 50,242
Total	$ 50,242	$ —	$ —	$ 50,242

As of December 31, 2018, the amortized cost and estimated fair value of the Company's available-for-sale securities by contractual maturity are shown below (in thousands):

	Amortized Cost	Estimated Fair Value
Marketable securities maturing:		
In one year or less	$ 83,270	$ 83,250
Total marketable securities	$ 83,270	$ 83,250

The Company determined that the gross unrealized losses on its marketable securities as of December 31, 2018 were temporary in nature. The Company currently does not intend to sell these securities prior to maturity and does not consider these investments to be other-than-temporarily impaired at December 31, 2018. There were no sales of available-for-sale securities in any of the periods presented.

4. Balance Sheet Components

Property and Equipment, Net

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

	December 31, 2018	December 31, 2017
Leasehold improvements	$ 3,268	$ 155
Furniture, laboratory and office equipment	2,043	1,242
Computer equipment	219	34
Construction in progress	—	464
Total property and equipment	5,530	1,895
Less accumulated depreciation and amortization	(935)	(355)
Property and equipment, net	$ 4,595	$ 1,540

Under the terms of its lease for office and laboratory space at 4000 Shoreline Court, South San Francisco, the Company received an incentive from the landlord for $3.2 million to construct leasehold improvements, which have been recorded in fixed assets and as deferred rent in other liabilities that will be amortized over the remaining lease term.

Depreciation expense was $0.7 million for the year ended December 31, 2018, $0.2 million for the year ended December 31, 2017 and $0.2 million for the year ended December 31, 2016.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31, 2018	December 31, 2017
Accrued preclinical and research costs	$ 1,146	$ 108
Accrued clinical costs	434	340
Accrued employee-related costs	736	422
Accrued professional services	138	—
Other	224	41
Accrued liabilities	$ 2,678	$ 911

5. Redeemable Convertible Preferred Stock

In connection with the completion of the Company's IPO in June 2018, all outstanding shares of convertible preferred stock converted into 12,263,126 shares of common stock.

6. Stock-Based Compensation

Stock Incentive Plans

2018 Equity Incentive Plan

In June 2018, the Company's board of directors adopted and its stockholders approved the 2018 Equity Incentive Plan (the "2018 Plan"), which became effective as of June 20, 2018, at which point no further grants will be made under the 2015 Equity Incentive Plan (the "2015 Plan") described below. Under the 2018 Plan, the Company may grant incentive stock options ("ISOs"), nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, restricted stock units ("RSUs") and other stock-based awards for the purchase of that number of shares of common stock. As of December 31, 2018, 85,621 options to purchase common stock and 10,189 RSUs have been granted and 1,802,145 shares were available for future issuance under the 2018 Plan.

Initially, subject to adjustment as provided in the 2018 Plan, the aggregate number of shares of the Company's common stock that may be issued pursuant to stock awards under the 2018 Plan will not exceed 4,000,000 shares, which is the sum of (i) 1,600,692 shares plus (ii) the number of shares reserved, and remaining available for issuance, under the 2015 Plan at the time the 2018 Plan became effective and (iii) the number of shares subject to stock options or other stock awards granted under the 2015 Plan that expire, terminate, are forfeited or otherwise not issued, or are withheld to satisfy a tax withholding obligation in connection with an award or to satisfy a purchase or exercise price of an award (such as upon the expiration or termination of a stock award prior to vesting). The number of shares of the Company's common stock reserved for issuance under the 2018 Plan will automatically increase on January 1 of each year, continuing through and including January 1, 2028, by 5% of the total number of shares of capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under the 2018 Plan is 12,500,000 shares.

2015 Equity Incentive Plan

The Company's 2015 Equity Incentive Plan provided for the granting of ISOs and NSOs to employees, directors and consultants at the discretion of the board of directors. The 2015 Plan was terminated as to future awards in June 2018, although it continues to govern the terms of options that remain outstanding under the 2015 Plan.

No additional stock awards will be granted under the 2015 Plan, and all outstanding stock awards granted under the 2015 Plan that are repurchased, forfeited, expire or are cancelled will become available for grant under the 2018 Plan in accordance with its terms.

Options granted under the 2015 Plan expire no later than 10 years from the date of grant. Options granted under the 2015 Plan vest over periods determined by the board of directors, generally over four years. The 2015 Plan allows for early exercise of certain options prior to vesting. Upon termination of employment, the unvested shares are subject to repurchase at the original exercise price. As of December 31, 2018, options to purchase 2,095,845 shares of common stock were outstanding under the 2015 Plan.

2018 Employee Stock Purchase Plan

In June 2018, the Company's board of directors and its stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"), which became effective as of June 20, 2018. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"). The number of shares of common stock initially reserved for issuance under the ESPP was 200,000 shares. The ESPP provides for an annual increase on the first day of each year beginning in 2019 and ending in 2028, in each case subject to the approval of the board of directors, equal to the lesser of (i) 1% of the shares of common stock outstanding on the last day of the prior fiscal year or (ii) 375,000 shares; provided, that prior to the date of any such increase, the board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). As of December 31, 2018, no shares of common stock had been issued under the ESPP and 200,000 shares remained available for future issuance under the ESPP. The option price per share of common stock to be paid by a participant upon exercise of the participant's option on the applicable exercise date for an offering period shall be equal to 85% of the lesser of the fair market value of a share of common stock on (a) the applicable grant date or (b) the applicable exercise date. The Board authorized an initial offering beginning on November 16, 2018 and ending on May 15, 2019. Following the end of the initial offering, a new offering will automatically begin on the day that immediately follows the conclusion of the preceding offering.

Stock Option Activity

The following table summarizes activity under the Company's stock option plan and related information (in thousands, except share and per share amounts):

	Number of Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2017	1,213,010	$ 1.54	8.7	$ 999
Options granted	1,121,901	$ 5.93		
Options exercised	(142,528)	$ 1.54		$ 370
Options cancelled	(10,917)	$ 0.90		
Outstanding at December 31, 2018	2,181,466	$ 3.80	8.5	$ 43,189
Vested and exercisable at December 31, 2018	833,679	$ 2.00	7.7	$ 18,008

The weighted average grant date fair value of options granted during the years ended December 31, 2018 and 2017 was $4.23 and $1.61 per share, respectively. The 2015 Plan allows for early exercisable option grants, which permit the grantee to exercise a stock option in exchange for stock before the requisite service is provided (e.g., before the award is vested under its original terms); however, such arrangements permit the Company to subsequently repurchase such shares at the exercise price if the vesting conditions are not satisfied. To date, the Company has made such grants only to non-employee board members. The total intrinsic value of exercised stock options during the years ended December 31, 2018 and 2017 was $370,000 and $0, respectively. The aggregate intrinsic value is calculated as the difference between the exercise price and the estimated fair value of the Company's common stock at the date of exercise.

Early Exercise Stock Purchase Agreements

As of December 31, 2018 and 2017, there were 68,349 and 45,224, respectively, of nonvested common shares outstanding that were exercised early and subject to repurchase by the Company at the original issuance price upon termination of the stockholder's services. The right to repurchase these shares generally lapses with respect to 25% of the shares underlying the option after the applicable vesting commencement date and 1/48 of the shares underlying the original grant per month for 36 months thereafter. The shares purchased pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be issued until those shares vest. The cash received in exchange for exercised and nonvested shares related to stock options granted is recorded as a liability for the early exercise of stock options on the balance sheets. As of December 31, 2018 and 2017, the Company recorded in other current liabilities $112,000 and $18,000, respectively, associated with shares issued upon the early exercise of stock options that are subject to repurchase.

Restricted Stock Units Granted to Employees

During the year ended December 31, 2018, the Company granted RSUs to certain employees to receive 10,189 shares of common stock pursuant to the 2018 Plan with a weighted-average estimated grant-date fair value of $17.75 per share. These RSUs were fully vested on the grant date. The valuation for these RSUs totaled $181,000 and was recognized as stock-based compensation expense in June 2018. There were no RSUs granted during the year ended December 31, 2017.

Stock Options Granted to Employees That Contain Performance Condition

During year ended December 31, 2018, the Company granted options to two of its executive officers to purchase an aggregate 115,657 shares of common stock that vested fully upon the closing of the Company's IPO on June 25, 2018. The aggregate fair value of these options was estimated at $474,000 and was recognized as stock-based compensation expense in June 2018. There were no such options granted that contained performance condition during the year ended December 31, 2017.

Restricted Stock

In addition to the nonvested common shares outstanding described above at "Early Exercise Stock Purchase Agreements," the Company issued restricted stock to its founders. The fair value of restricted stock on the issuance date is deemed equal to the cash consideration paid by the founders. Restricted stock vests over a four-year period from the applicable vesting commencement date. The following summarizes the activity of nonvested restricted stock:

	Number of Shares
Nonvested—December 31, 2017	193,394
Vested	(172,486)
Nonvested—December 31, 2018	20,908

Stock-Based Compensation Expense

Total stock-based compensation recognized by function was as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
General and administrative	$ 1,151	$ 110	$ 64
Research and development	842	93	64
Total stock-based compensation expense	$ 1,993	$ 203	$ 128

As of December 31, 2018, the unrecognized stock-based compensation cost and the estimated weighted average amortization period, using the straight-line attribution method, was as follows (dollars in thousands):

	Unrecognized Compensation Cost	Weighted Average Remaining Amortization Period (Years)
Employee options	$ 3,977	2.8
Nonemployee options	4	0.4
Total unrecognized stock-based compensation expense	$ 3,981	

The fair value of the employee stock options granted is calculated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Options			ESPP		
	Year ended December 31,			Year ended December 31,		
	2018	2017	2016	2018	2017	2016
Expected term (years)	5.5 - 6.1	6.1	6.1	0.5	—	—
Expected volatility	82.0 - 83.2%	89.8%	80.4%	74.3%	—	—
Risk-free interest rate	2.6 - 3.1%	2.0%	1.4%	2.5%	—	—
Expected dividend yield	—	—	—	—	—	—

The expected term of options granted represents the period of time that options granted are expected to be outstanding and was determined by calculating the midpoint between the date of vesting and the contractual life of each option. The expected term of the ESPP rights is equal to the six-month look-back period. Volatility is based on the average historical volatility of a peer group of public companies over the expected term. The peer group was selected on the basis of operational and economic similarity with the Company's principal business operations. The risk-free interest rate for the expected term of the options is based on the U.S. Treasury yield curve with a maturity equal to the expected term in effect at the time of grant. The Company has not paid, and does not anticipate paying, cash dividends on its shares of common stock; therefore, the expected dividend yield is zero.

7. Commitments & Contingencies

Contractual Obligations and Other Commitments

In August 2017, the Company entered into a lease agreement to lease 24,357 square feet of combination laboratory and office space in 4000 Shoreline Court, South San Francisco, California. The lease commenced on March 1, 2018 and terminates on February 28, 2025.

The Company recognizes rent expense on a straight-line basis over the noncancelable lease period and records the difference between cash rent payments and the recognition of rent expense as deferred rent liability.

Future minimum lease payments are as follows as of December 31, 2018 (in thousands):

Year ending December 31:		
2019	$	1,453
2020		1,497
2021		1,542
2022		1,588
2023		1,635
Thereafter		1,966
Total future minimum lease payments	$	9,681

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by California corporate law. The Company currently has directors' and officers' insurance.

8. License Agreement

In June 2015, the Company entered into an exclusive license agreement with Onyx Therapeutics, Inc. ("Onyx"), a wholly owned subsidiary of Amgen, Inc., a related party, for a worldwide, exclusive license under certain patents, and a non-exclusive license to certain know-how, in each case controlled by Onyx and relating to the Company's immunoproteasome program. The Company may be required to make future payments of up to $172.5 million upon achievement of certain development and commercial milestones, as well as pay royalties in the mid to high single digits on future annual net sales, if any**.**

9. Defined Contribution Plan

The Company has a qualified 401(k) Savings and Investment Plan (the Plan) whereby employees may contribute up to the lesser of $53,000 or 100% of their pre-tax compensation. The total contributed amount from the employees is only up to Federal annual limits. The Company matches $1.00 for every $1.00 contributed to the Plan by participants up to 4% of base compensation (subject to statutory limits). During the years ended December 31, 2018, 2017 and 2016, the Company contributed $167,000, $77,000 and $62,000, respectively, to the Plan.

10. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2018, 2017 and 2016. The U.S. federal deferred tax assets generated from the Company's net operating losses have been fully reserved, as the Company believes it is not more likely than not that the benefit will be realized. The Tax Cuts and Jobs Act of 2017 (the "Tax Act") contains tax law changes that are effective in tax years 2018 and onward. During 2018, the Company finalized its analysis of the provisional impact associated with the remeasurement of deferred tax assets. There was no change in the provisional remeasurement amount previously recorded in 2017.

The following table presents domestic and foreign components of net loss for the periods presented (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Domestic	$ (23,047)	$ (7,551)	$ (7,009)
Foreign	(120)	(966)	(1,981)
Total	$ (23,167)	$ (8,517)	$ (8,990)

In December 2015, the Protecting Americans from Tax Hikes Act of 2015 ("PATH") was signed into law, which created several new research and development ("R&D") tax credit provisions, including allowing qualified small businesses to utilize the R&D credit against the employer's portion of payroll tax up to a maximum of $250,000 per year. The Company qualified as a small business under PATH for both 2016 and 2017. During the year ended December 31, 2018, the Company has utilized $175,000 of R&D tax credits as a reduction of payroll expenses to offset its payroll tax liabilities.

The effective tax rate of the provision for income taxes differs from the federal statutory rate as follows:

	Year Ended December 31,		
	2018	2017	2016
Federal statutory income tax rate	21.0 %	34.0 %	34.0 %
State taxes, net of federal benefit	6.4	6.0	5.8
Foreign tax rate differential	0.1	(0.5)	(0.9)
Permanent differences	0.3	(3.8)	(2.0)
Research and development credit	1.4	2.5	2.6
Federal rate change impact	0.0	(31.4)	0
Change in valuation allowance	(29.2)	(6.8)	(39.5)
Provision for income taxes	— %	— %	— %

The components of the deferred tax assets and liabilities are as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Deferred tax assets			
Reserves and accruals	$ 1,009	$ 169	$ 20
Net operating loss carry forwards	10,985	6,802	6,607
Research and development credit carryforwards	1,194	515	453
Gross deferred tax assets	13,188	7,486	7,080
Valuation allowance	(12,560)	(7,434)	(7,036)
Net deferred tax assets	628	52	44
Deferred tax liabilities			
Property and equipment	(628)	(52)	(44)
Net deferred tax	$ —	$ —	$ —

Realization of the deferred tax assets is dependent upon future taxable income. Since the amount and timing of future income are uncertain, the net deferred tax assets, as of December 31, 2018, and December 31, 2017 have been fully offset by a valuation allowance. The valuation allowance increased approximately $5.1 million, $0.4 million and $3.6 million during the years ended December 31, 2018, 2017, and 2016.

As of December 31, 2018, the Company had federal net operating loss ("NOL") carryforward of $44.2 million and a federal research and development tax credit carryforward of $0.6 million. If not utilized sooner, the federal NOL generated through December 31, 2017 and tax credit carryforwards will expire, beginning in 2035. Federal net operating loss carryforwards of $22.2 million generated for year ending December 31, 2018, carryforward indefinitely. As of December 31, 2018, the Company had a state NOL carryforward of $17.3 million, which will expire beginning in 2035, and a state research and development tax credit carryforward of $0.7 million, which does not expire.

As of December 31, 2018, the Company also had accumulated Australian tax losses of $1.8 million available for carry forward against future earnings, which under relevant tax laws do not expire but may not be available under certain circumstances.

In general, if the Company experiences a greater than 50 percentage point aggregate change in ownership over a three-year period (a Section 382 ownership change), utilization of the Company's pre-change NOL carryforwards is subject to an annual limitation under Section 382 of the Code and similar California laws. The annual limitation generally is determined by multiplying the value of the Company's stock at the time of such ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. The Company has not utilized any NOL carryforwards through December 31, 2018. In addition, the Company's deferred tax assets are subject to a full valuation allowance, and thus no benefit for deferred tax assets is recorded on the Company's books. The Company's ability to use the remaining NOL carryforwards may be further limited if the Company experiences a Section 382 ownership change as a result of future changes in the Company's stock ownership.

No liability related to uncertain tax positions is recorded on the financial statements. Since inception, there have been no interest charges or penalties related to unrecognized tax benefits.

The Company files income tax returns in the United States federal jurisdiction, the State of California and Australia. The Company currently has no federal, state or other jurisdictional tax examinations in progress. The Company did not recognize any accrued interest and penalties related to gross unrecognized tax benefits related to the year ended December 31, 2018. All years are open for examination by federal, state and Australian authorities.

11. Net Loss Per Share

Net Loss Per Share

The following table sets forth the calculation of basic and diluted net loss per share during the periods presented (in thousands, except share and per share data):

	Year Ended December 31,		
	2018	2017	2016
Numerator:			
Net loss	$ (23,167)	$ (8,517)	$ (8,990)
Denominator:			
Weighted-average shares of common stock outstanding	10,264,584	599,291	338,446
Net loss per share, basic and diluted	$ (2.26)	$ (14.21)	$ (26.56)

The following outstanding shares of common stock equivalents were excluded from the computation of the diluted net loss per share for the periods presented because their effect would have been anti-dilutive:

	Year Ended December 31,		
	2018	2017	2016
Redeemable convertible preferred stock on an if converted basis	—	12,263,126	5,966,753
Stock options to purchase common stock	2,181,466	1,213,010	680,333
Common stock subject to future vesting	89,257	238,618	485,119
Total	2,270,723	13,714,754	7,132,205

12. Selected Quarterly Financial Information (Unaudited)

The following amounts are in thousands, except per share amounts:

	Quarter Ended			
(in thousands, except per share amount)	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
	(Unaudited)			
Operating Expenses	$ 5,086	$ 6,950	$ 6,264	$ 6,426
Net loss	$ (4,947)	$ (6,775)	$ (5,663)	$ (5,782)
Net loss per share, basic and diluted	$ (6.53)	$ (3.31)	$ (0.30)	$ (0.30)

	Quarter Ended			
(in thousands, except per share amount)	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
	(Unaudited)			
Operating Expenses	$ 2,257	$ 1,881	$ 2,192	$ 2,419
Net loss	$ (2,257)	$ (1,880)	$ (2,080)	$ (2,300)
Net loss per share, basic and diluted	$ (4.43)	$ (3.30)	$ (3.31)	$ (3.34)

Basic and diluted net loss per share is computed independently for each of the quarters presented. Therefore, the sum of quarterly basic and diluted per share amounts may not equal annual basic and diluted net loss per share amounts.

Exhibit 10.13

CONFIRMATION OF LEASE TERMS

This CONFIRMATION OF LEASE TERMS (**"Confirmation"**) is made and entered into effective as of March 1, 2018, by and between AP3-SF1 4000 SHORELINE, LLC, a Delaware limited liability company (**"Landlord"**) and KEZAR LIFE SCIENCES, INC., a Delaware corporation (**"Tenant"**).

R E C I T A L S:

A. Landlord and Tenant entered into that certain Lease dated as of August 16, 2017 (the "Lease") pursuant to which Landlord leased to Tenant and Tenant leased from Landlord certain "Premises", as described in the Lease, in that certain building located at 4000 Shoreline Court, South San Francisco, California 94080.

B. Except as otherwise set forth herein, all capitalized terms used in this Confirmation shall have the same meaning as such terms have in the Lease.

C. Landlord and Tenant desire to amend the Lease to confirm the commencement and expiration dates of the term, as hereinafter provided.

NOW, THEREFORE, in consideration of the foregoing Recitals and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Confirmation of Dates. The parties hereby confirm that (a) the Premises are Ready for Occupancy, and (b) the term of the Lease commenced as of February 27, 2018 for a term of eighty-four (84) months ending on February 28, 2025 (unless sooner terminated as provided in the Lease. Tenant shall commence to pay rent on February 27, 2018 (**"Rent Commencement Date"**).

2. No Further Modification. Except as set forth in this Confirmation, all of the terms and provisions of the Lease shall remain unmodified and in full force and effect.

[Remainder of Page Intentionally Left Blank; Signatures Follow]

IN WITNESS WHEREOF, THIS Confirmation has been executed as of the day and year first above written.

"Landlord":
AP3-SF1 4000 SHORELINE, LLC,
a Delaware limited liability company

By: /s/ W. Neil Fox, III
Name: W. Neil Fox, III
Its: Chief Executive Officer

"Tenant":
KEZAR LIFE SCIENCES, INC.,
a Delaware CORPORATION

By: /s/ John Fowler
Name: John Fowler
Its: CEO

By: /s/ Michael Wolfe
Name: Michael Wolfe
Its: Director of Finance & Operations

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Kezar Life Sciences, Inc.:

We consent to the incorporation by reference in the registration statement (No. 333-225769) on Form S-8 of Kezar Life Sciences, Inc. of our report dated March 26, 2019, with respect to the consolidated balance sheets of Kezar Life Sciences, Inc. as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes, collectively, the consolidated financial statements, which report appears in the December 31, 2018 annual report on Form 10-K of Kezar Life Sciences, Inc.

/s/ KPMG LLP

San Francisco, California
March 26, 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, John Fowler, certify that:

1. I have reviewed this Form 10-K of Kezar Life Sciences, 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(s) 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)) 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(s) 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 26, 2019

By: /s/ John Fowler
John Fowler
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, Marc Belsky, certify that:

1. I have reviewed this Form 10-K of Kezar Life Sciences, 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(s) 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)) 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(s) 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 26, 2019

By: /s/ Marc Belsky
Marc Belsky
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), John Fowler, Chief Executive Officer of Kezar Life Sciences, Inc. (the "Company"), and Marc Belsky, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

(1) The Company's Annual Report on Form 10-K for the year ended December 31, 2018, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Date: March 26, 2019

/s/ John Fowler
John Fowler
Chief Executive Officer
(Principal Executive Officer)

/s/ Marc Belsky
Marc Belsky
Chief Financial Officer
(Principal Financial Officer)