# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 10-K

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

For the fiscal year ended December 31, 2021

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-38542

# **Kezar Life Sciences, Inc.**

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

4000 Shoreline Court, Suite 300 South San Francisco, CA

47-3366145 (I.R.S. Employer Identification No.)

94080

(Address of principal executive offices)		(Zip Code)			
	Registrant's	s telephone number, including area	code: (650) 822-5600		
Securities registered pursuant to Section	on 12(b) of the Act:		<del>_</del>		
Title of each	ı class	Trading symbol	Name of each exchange on which registered		
Common Stock, \$0.	001 par value	KZR	The Nasdaq Stock Market LLC		
Securities registered pursuant to Section	on 12(g) of the Act: <b>None</b>				
ndicate by check mark if the Registra	nt is a well-known seasoned i	ssuer, as defined in Rule 405 of the Securities	Act. Yes ⊠ No □		
ndicate by check mark if the Registra	nt is not required to file repor	ts pursuant to Section 13 or 15(d) of the Act. Y	⁄es □ No ⊠		
		orts required to be filed by Section 13 or 15(d) orts), and (2) has been subject to such filing red	of the Securities Exchange Act of 1934 during the preceding 12 mortuirements for the past 90 days. Yes $\boxtimes$ No $\square$	iths (or for	
		onically every Interactive Data File required to Registrant was required to submit such files). Y	be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of Yes $\boxtimes$ No $\square$	this chapte	
		filer, an accelerated filer, a non-accelerated filer, an on-accelerated filer, and "emerging growth co	er, smaller reporting company, or an emerging growth company. See ompany" in Rule 12b-2 of the Exchange Act.	the	
Large accelerated filer			Accelerated filer		
Non-accelerated filer	$\boxtimes$		Smaller reporting company	Σ	
Emerging growth company					
f an emerging growth company, indica	ate by check mark if the regis	trant has elected not to use the extended transi	tion period for complying with any new or revised financial account	ing	

standards provided pursuant to Section 13(a) of the Exchange Act. ⊠

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Acct). Yes  $\square$  No  $\boxtimes$ 

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 Global

Select Market on June 30, 2021, was approximately \$252 million. The number of shares of Registrant's Common Stock outstanding as of March 15, 2022 was 56,712,716.

# DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the 2022 Annual Meeting of Stockholders of the registrant, or the Proxy Statement, 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, 2021.

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In this report, unless otherwise stated or the context otherwise indicates, references to "Kezar Life Sciences," "Kezar," "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," "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:

- statements regarding the impact of the ongoing COVID-19 pandemic and its effects on our operations, research and development, clinical trials and financial position, and its potential effects on the operations of third-party manufacturers, contract research organizations, other service providers, and collaborators with whom we conduct business;
- our plans to develop and commercialize our product candidates;
- the initiation, timing, progress and expected 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 or other technology on reasonable terms;
- our ability to maintain and establish collaborations or strategic relationships or obtain additional funding;
- the timing and likelihood of obtaining 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;
- the scope of protection we are able to establish and maintain for intellectual property rights and the duration of our patent rights covering our product candidates;
- developments or disputes concerning our intellectual property or other proprietary rights;
- the scalability and commercial viability of our manufacturing methods and processes:
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to compete in the markets for our product candidates;
- 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 immune-mediated diseases and cancer. We believe therapies that inhibit multiple drivers of disease by targeting fundamental upstream control processes within the cell have the potential for profound therapeutic benefit in a number of difficult-to-treat diseases. To that end, we are advancing two drug development programs that harness different master regulators of cellular function: the first targets the immunoproteasome which is responsible for protein degradation in cells of the immune system and drives many key aspects of immune cell function, and the second targets the Sec61 translocon, which is located on the endoplasmic reticulum and represents the beginning of the protein secretion pathway. Targeting these fundamental regulators of cellular function offers an attractive approach to treating many diseases.

Our lead product candidate, KZR-616, is a first-in-class selective immunoproteasome inhibitor that has completed Phase 1a testing in healthy volunteers and a Phase 1b trial in patients with systemic lupus erythematosus, or SLE. We are leveraging its broad therapeutic potential in two Phase 2 clinical trials, MISSION and PRESIDIO, treating patients with severe autoimmune diseases of high unmet medical need. The Phase 2 portion of our MISSION clinical trial is evaluating KZR-616 in patients with lupus nephritis, or LN. The PRESIDIO Phase 2 clinical trial is evaluating KZR-616 in dermatomyositis, or DM, and polymyositis, or PM, indications for which KZR-616 has been granted orphan drug designation, or ODD, by the U.S. Food and Drug Administration, or FDA. Both MISSION and PRESIDIO are fully enrolled with topline data expected in the second quarter of 2022. Based on Phase 1 clinical data generated to date with KZR-616, as well as preclinical data with selective immunoproteasome inhibitors, we believe that KZR-616 has the potential to address multiple chronic immune-mediated diseases. We intend to identify additional immune-mediated disease indications where a proof of principle exists to further develop KZR-616. The International Nonproprietary Name (INN) of zetomipzomib has been selected as the proposed nonproprietary name for KZR-616.

We believe that the immunoproteasome is a validated target for the treatment of a wide variety of immune-mediated diseases given its ability to regulate multiple drivers of the inflammatory disease process. Many inflammatory disorders are currently treated one cytokine or cell type at a time, but the immunoproteasome affects a broad spectrum of immune regulators. We have seen encouraging clinical activity and biomarker data in the SLE and LN patients who received KZR-616 in the MISSION trial to date. The safety and tolerability profiles of KZR-616 has been favorable and consistent with the needs for a long-term therapy.

Our oncology product candidate, KZR-261, is being studied in an open-label Phase 1 clinical trial designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, as well to explore preliminary anti-tumor activity. This study will be conducted in two parts: dose escalation in patients with locally advanced or metastatic solid malignancies, and dose expansion in patients with selected tumor types. KZR-261 is the first clinical candidate from our novel research platform targeting the Sec61 translocon and the protein secretion pathway for the discovery and development of small molecule therapeutics for oncology and autoimmune indications. KZR-261 has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies by targeting multiple pathways driving tumor growth and survival. We believe this discovery platform has the potential to yield additional small molecule product candidates with the ability to inhibit multiple pathways as a single agent, as well as compounds designed to selectively inhibit a single secreted or transmembrane protein of interest. If successfully developed and approved, these small molecules could serve as alternatives to currently marketed biologic therapeutics to act as cytotoxic anti-cancer agents or to block the secretion of novel targets of interest in immuno-oncology or inflammation.

## **Our Pipeline**

**KZR-616** 

The following table sets forth the status of our product candidates and discovery program:

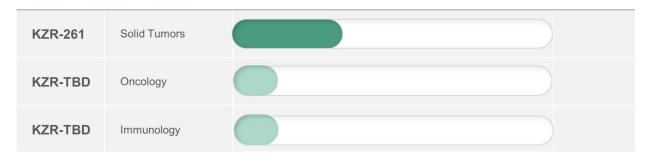
COMPOUND	THERAPEUTIC INDICATION	DEVELOPMENT STAGE				MILESTONES
		PRE- CLINICAL	PHASE 1	PHASE 2	PHASE 3	MILLOTONES
Selective Immunoproteasome Inhibition						
	Lupus Nephritis (LN)	# MISSIO	N			Q2 2022 (Top-Line Data)

**PRESIDIO** 

# Protein Secretion Inhibition

Dermatomyositis (DM)

Polymyositis (PM)



## **KZR-616: Selective Immunoproteasome Inhibitor**

We believe that KZR-616 is the only selective immunoproteasome inhibitor that is in clinical trials for the treatment of autoimmune disorders. If successfully developed and approved, KZR-616 may have the ability to become standard of care across a range of immune-mediated diseases based on the following key attributes:

 broad immunomodulatory activity that may provide meaningful therapeutic benefit without immunosuppression across a range of treatable and currently untreatable immune-mediated diseases;

Q2 2022

(Top-Line Data)

- subcutaneous, once weekly dosing schedule which is amenable to patient self-administration with the potential of less frequent dosing for chronic use;
- rapid drug clearance from the plasma with a half-life of less than five hours;
- no drug-drug interactions predicted;
- no teratogenicity or reproductive toxicity observed in preclinical studies;
- · full recovery of immunoproteasome activity occurs within three to seven days following dose administration; and
- unique chemical structure leads to highly specific inhibition of the immunoproteasome without known off-target effects.

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, in June 2015, or the Onyx License Agreement. Patent coverage for KZR-616 extends to at least 2034. KZR-616 is the result of long-term research and development efforts led by our President, Co-Founder, and Chief Scientific Officer, Christopher Kirk Ph.D., which originated at Onyx.

#### Clinical Development of KZR-616

We are focusing the initial development of KZR-616 in chronic and severe immune-mediated diseases where limited treatment options exist. Due to its broad immunomodulatory profile, we believe that KZR-616 has the potential to address multiple chronic-immune mediated diseases.

#### MISSION

The Phase 2 portion of MISSION is an open-label trial to demonstrate the responder rate of KZR-616 in patients with active LN. During the 24-week treatment period, patients receive 60 mg of KZR-616 subcutaneously once weekly (first dose of 30 mg) in addition to standard background therapy. Patients in the MISSION Phase 2 trial do not receive KZR-616 as part of an "induction" therapy, which represents a significant difference in comparison to other recently published trials in LN. End of treatment assessments occur at Week 25. The primary efficacy endpoint for the trial is the proportion of patients achieving a renal response measured by a 50% or greater reduction in urine protein to creatinine ratio, or UPCR, at end of treatment. The secondary efficacy endpoint for the trial is the number of patients with a complete renal response, or CRR, and partial renal response, or PRR. We completed target enrollment of 20 patients in November 2021. Top-line data are expected in the second quarter of 2022.

Lupus nephritis is one of the most serious complications of systemic lupus erythematosus. LN is a disease comprising a spectrum of vascular, glomerular, and tubulointerstitial lesions and develops in approximately 50% of SLE patients within 10 years of their initial diagnosis. LN is associated with considerable morbidity, including an increased risk of end-stage renal disease requiring dialysis or renal transplantation and an increased risk of death. Management of this disease typically consists of induction therapy to achieve remission and long-term maintenance therapy to prevent relapse. There are FDA-approved drugs for the treatment of LN. However, an unmet need still exists for treatments that can reduce disease activity quickly and without widespread immunosuppression.

## **PRESIDIO**

PRESIDIO is a Phase 2 randomized, placebo-controlled, double-blind, crossover clinical trial to evaluate the safety, tolerability, efficacy, pharmacokinetics and pharmacodynamics of KZR-616 in patients with active DM or PM. During the 32-week treatment period, patients receive either 45 mg of KZR-616 or placebo subcutaneously once weekly for 16 weeks followed by a crossover to the other treatment arm for an additional 16 weeks (the first two doses are at 30 mg). The primary efficacy endpoint of PRESIDIO is the mean change from beginning to end of treatment with KZR-616 in the Total Improvement Score (TIS) which ranges from 0 to 100. We completed target enrollment of 24 patients in August 2021. Top-line data from PRESIDIO are expected in the second quarter of 2022. We believe that KZR-616 has the potential to be developed into a treatment for patients with DM and PM, which is in-part supported by preclinical data in a mouse model of DM and PM that demonstrated immunoproteasome inhibition and improved muscle function.

Patients completing PRESIDIO have the opportunity to enroll into an open-label extension, or OLE, study to continue receiving KZR-616 treatment for up to a total of 96 weeks. In December 2021, we introduced at-home self-administration of KZR-616 for patients in the OLE study.

Dermatomyositis and polymyositis are two of the five types of idiopathic inflammatory myopathies. The FDA has granted ODDs for KZR-616 for treatment of both DM and PM, and KZR-616 is the only investigational new drug to receive ODD in both indications. These diseases are chronic, debilitating, progressive inflammatory autoimmune myopathies that are distinguished by inflammation of the muscles, as well as the skin in DM. Between 30,000 and 120,000 people in the United States are living with DM or PM and the reality of increased morbidity and associated mortality resulting from their disease. While debilitating muscle weakness is the hallmark of these myopathies, including compromised muscles of respiration, DM and PM can also result in other equally disabling internal organ system dysfunctions. The aim of treatment for these diseases is to suppress inflammation, increase muscle strength and prevent long-term damage to muscles and extramuscular organs. Treatment options are limited for patients with DM, and there are currently no approved therapeutics for PM.

## **MISSION Phase 2 Interim Results**

In November 2021, we reported interim results from the MISSION Phase 2 clinical trial, in which five patients had reached the end of treatment, and ten patients had reached week 13 of treatment. The interim results showed a clinically meaningful renal response at the end of treatment for this subset of patients:

- 3 of 5 patients achieved a 50% or greater reduction in UPCR at week 25 compared to baseline, the primary efficacy endpoint of the clinical trial.
- 4 of 5 patients who completed treatment at week 25 with KZR-616 demonstrated clinically meaningful reduction in proteinuria to less than 0.8 UPCR.

- 2 patients showed a CRR and had a reduction of absolute proteinuria values to equal to or less than 0.5 UPCR.
- 2 patients showed a PRR and had a reduction of absolute proteinuria values to between 0.5 and 0.8 UPCR.
- Clinically meaningful reductions in UPCR were observed in 5 of 10 patients at week 13 of KZR-616 and included improvements in key disease biomarkers.
- KZR-616 was well tolerated over the six-month treatment period.
  - No new safety signals were observed in the Phase 2 portion of the MISSION trial.
  - Adverse events were generally mild-to-moderate (Grade 1 or 2).
  - There were no study discontinuations due to drug related adverse events. There was one temporary interruption of study drug due to a Grade 3 serious adverse event, the occurrence of a migraine, and one discontinuation unrelated to the study drug.

The above interim data from the MISSION Phase 2 clinical trial are preliminary and will require confirmation in additional patients, as well as longer follow-up, to draw any meaningful clinical conclusion and are subject to routine audit and verification procedures that could result in material changes in the final data. Top-line data from this trial are expected in the second quarter of 2022.

#### **MISSION Phase 1b Results**

In June 2021, we presented the results of the completed MISSION Phase 1b clinical trial of KZR-616. The Phase 1b dose escalation study evaluated doses of 45 mg to 75 mg of KZR-616 administered subcutaneously once weekly in a total of 47 patients with SLE, including 2 patients with active proliferative lupus nephritis. 35 of 47 patients completed the study across six cohorts in which patients received 13 weekly doses of KZR-616 and were followed for an additional 12 weeks.

Encouraging trends in exploratory efficacy were confirmed across cohorts, including the improvement of seven SLE-specific disease activity scores. Mean disease activity scores improved in patients who completed the 13-week treatment period (n=35), and improvement in disease activity persisted following the end-of-treatment. Improvement in key biomarkers indicating a reduction in disease activity were also observed. 8 of 8 patients with elevated anti-double-stranded DNA antibody, or anti-dsDNA, levels at baseline had a reduction in anti-dsDNA levels. Improvement in disease activity persisted following the end-of-treatment. The safety and tolerability of KZR-616 was favorable and consistent with needs for a long-term therapy. Most treatment emergent adverse events occurred early and diminished with later doses with the most common being injection site reactions.

Two of two patients in this trial with active proliferative LN had a greater than 50% reduction in UPCR and experienced reductions in anti-dsDNA levels and SLEDAI-2K scores (SLE Disease Activity Index 2000). Biomarker data on these two patients with LN show baseline elevation of urinary CD163, or uCD163, a marker of inflammatory activity in the kidney in patients with LN. Both patients also had a reduction in uCD163, suggesting an important anti-inflammatory effect not achieved with the background therapies.

## Safety Profile

Safety and tolerability are monitored across clinical trials of KZR-616 by study-specific data monitoring committees. To date, injection site reactions, or ISRs, are the most common treatment emergent adverse event. The ISRs occur at the time and site of injection, are described as redness, pain, itchiness or indurated. The ISRs are not vasculitic or immunogenic. No clinically significant laboratory abnormalities have been noted; and specifically, we have not observed cytopenias, transaminase abnormalities or renal dysfunction. In addition, no opportunistic infections have been observed to date. With respect to tolerability, a small number of patients (2 of 100 healthy volunteers in our Phase 1a studies; and 2 of 93 patients in our MISSION and PRESIDIO studies) have experienced symptoms suggestive of a systemic injection reaction related to or probably related to KZR-616 at a dose of 60 mg. Based on these observations, we introduced a dosing regimen where patients receive an initial dose of 30 mg of KZR-616 followed by administration of the target dose of 45 mg, 60 mg or 75 mg of KZR-616. The introduction of an initial "step up" dose, together with prophylactic and supportive measures such as oral hydration with electrolyte-rich drinks, has substantially mitigated this early concern. Some patients have reported nausea and occasional vomiting on the day of dosing, which has also been mitigated with the use of optional oral hydration and/or oral or sublingual antiemetics.

# **Investigator-Initiated Single-Patient Study**

In November 2021, Samir Parikh, M.D., an Associate Professor, Division of Nephrology at The Ohio State University, presented a case report on an investigator-initiated clinical study of KZR-616 where Dr. Parikh treated a single patient with LN who previously received KZR-616 under the Phase 1b portion of MISSION. Following completion of the MISSION Phase 1b study, the patient experienced worsening course of disease and return to nephrotic range proteinuria. Specifically, the patient's UPCR went from 0.56 at three months following study completion to 5.5 at nine months following study completion. Dr. Parikh then started the patient on high dose prednisone of 40 mg/day for 30 days which was tapered to 15 mg/day until beginning the investigator-initiated clinical study.

With prednisone therapy, proteinuria improved from 5.5 to 2.4 and remained there until resuming treatment with KZR-616. Within 12 weeks of retreatment with KZR-616, the patient's UPCR reduced to below 0.5 with complete cessation of corticosteroids. Kezar was not the sponsor of this study and has not independently verified or audited these data.

#### Immune-mediated Diseases and Selective Inhibition of the Immunoproteasome

We are focusing our development efforts on immune-mediated diseases of high unmet need and intend to identify additional indications to develop KZR-616. Immune-mediated diseases are conditions which result from abnormal activity of the body's immune system. They are characterized by immune dysregulation, and the inappropriate activation of inflammatory cytokines is an underlying manifestation. This abnormal immune response can lead to activation of inflammatory T-cells and cytotoxic T-cells which can cause inflammation, tissue damage, organ damage, the generation of cytokines that are harmful to the surrounding tissue, or activation of macrophages, which can also lead to cytokine release, as well as cellular damage from free radicals.

Autoimmune disease is a subset of immune-mediated diseases whereby an immune response is directed against the body's own healthy cells and tissues. 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.

These inflammatory disorders are currently treated one cytokine or cell type at a time or with powerful immunosuppressive agents. Across all immune-mediated diseases, both large and small, there remain significant unmet medical needs and indications with no approved drugs beyond broadly prescribed corticosteroids and similar immunosuppressive regimens. These result in increased risk of infection and malignancy and a wide variety of side effects. In many autoimmune diseases, immunosuppressive regimens do not always induce high rates of clinically meaningful responses. Even if these agents are initially effective, over time patients often experience loss of response. Found predominantly in cells of the immune system, the immunoproteasome modulates multiple drives of inflammation in the immune-mediated disease process. Selectively inhibiting this master regulator of immune cells has the potential to reduce inflammation by reducing the production of key cytokines and downregulating the inflammatory activity of immune cells involved in immune-mediated diseases, such as T-cells and B-cells, without resulting in widespread immunosuppression.

Proteasomes are found in all cells of the body and 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. These active sites are responsible for cleaving and degrading proteins. KZR-616 is derived from medicinal chemistry efforts focused on potent and selective inhibition of the immunoproteasome-specific subunits LMP7 and LMP2.

In preclinical models of inflammation, selective inhibitors of the immunoproteasome were shown to block cytokine production and result in profound immunomodulatory therapeutic activity equivalent to or better than approved dual proteasome inhibitors without causing cytotoxicity. In over 15 peer-reviewed publications, our selective inhibitors of the immunoproteasome and related compounds have demonstrated strong therapeutic potential by blocking disease progressions in animal models multiple immune-mediated diseases. Additionally, this immunomodulatory response was broadly seen across many cell types of the immune system, including both T-cells and B-cells, and was demonstrated in a non-immunosuppressive manner. This is distinct from other agents currently used to treat autoimmunity, which typically target a single cytokine or immune cell type or are broadly immunosuppressive.

# **KZR-261: A First-In-Class Protein Secretion Inhibitor**

KZR-261 is a novel, first-in-class protein secretion inhibitor and the first clinical candidate nominated from our proprietary protein secretion platform. KZR-261 is a broad-spectrum agent that acts through direct interaction and inhibition of Sec61 activity. We have presented encouraging preclinical data with KZR-261 that highlight its potential as a new anti-cancer agent for the treatment of both solid and hematologic malignancies.

We have shown that KZR-261 can simultaneously inhibit multiple clinically relevant targets (for example, immune checkpoints and oncogenic factors) in vitro and inhibit tumor growth in vivo in multiple models, including tumors resistant to traditional chemotherapeutics. In preclinical studies, KZR-261 has been shown induce a direct anti-tumor effect and to modulate the tumor microenvironment. The direct anti-tumor effect of KZR-261 is driven by induction of cell death through proteotoxic stress and other factors, as well as the reduced expression of key growth factors and receptors driving tumor survival and proliferation. In addition, KZR-261 modulates the tumor microenvironment by reducing angiogenic factor expression (e.g., VEGF) and reducing immune checkpoint expression. The preclinical data generated with KZR-261 increases our belief that inhibiting the Sec61 translocon could be effective against a variety of solid and hematologic tumor types.

#### Clinical Development of KZR-261

In October 2021, we initiated an open-label Phase 1 clinical trial of KZR-261 in patients with solid tumor malignancies. The study is being conducted in two parts, dose escalation and dose expansion, and is designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, as well as to explore the preliminary anti-tumor activity of KZR-261 in patients with locally advanced or metastatic disease. Following safety review of all dose escalation cohorts and determination of the maximum tolerated dose or maximum administered dose, KZR-261 will be evaluated for safety and preliminary efficacy in four tumor-specific cohorts and one all-tumor cohort to determine doses recommended for Phase 2 studies.

## Discovery Platform: Inhibition of the Protein Secretion Pathway via the Sec61 Translocon

Our novel platform for drug discovery targets the Sec61 translocon and the protein secretion pathway to develop potential therapies for oncology, immuneoncology and autoimmune indications.

We believe that protein secretion inhibitors targeting the Sec61 translocon have the potential to replicate the activity of biologic therapies, induce multitarget inhibition, and be designed for oral bioavailability. We have generated a unique and powerful platform for exploitation of the Sec61 translocon as a drug target across a wide range of diseases. As a result of this drug discovery platform, we have generated multiple chemical classes of protein secretion inhibitors with activity in preclinical models of malignant diseases, immune-oncology, inflammation and viral infections. Our research has shown that multiple chemical series can be tuned to selectively target the interaction between unique protein signal sequences and Sec61.

The activity of the Sec61 translocon is a highly conserved process, as virtually all secreted and transmembrane proteins (between 5,000 and 7,000 proteins) utilize Sec61 to enter the endoplasmic reticulum and begin the process of transit to the cell surface. Each protein expresses a unique signal sequence or transmembrane domain. By blocking the functional interaction of signal sequences and Sec61, our tool compounds can inhibit the expression of multiple proteins simultaneously or induce selective inhibition of a small number of proteins. Many validated targets utilize the Sec61 translocon, including targets currently served only by biologic therapies, and our program holds the potential for best-in-class small molecule therapeutics against these targets.

We have highlighted our work from the protein secretion platform during several scientific and medical conferences, including the American Association of Cancer Research (AACR), American Society of Clinical Oncology (ASCO), American Society of Hematology (ASH), the International Cytokine and Interferon Society (ICIS) and the Society of Immunotherapy in Cancer (SITC). Our preclinical research on the Sec61 translocon demonstrated high degrees of potency against a large number of therapeutically relevant oncology, immuno-oncology, and inflammatory targets that are Sec61 client proteins, translating into broad anti-tumor or anti-inflammatory activity. Our discovery-stage Sec61 inhibitors have shown to induce anti-tumor activity against multiple hematologic tumor types without inducing cell death in normal cells or significant toxicity in animals. Our tool compounds also block inflammation in animal models of autoimmunity at doses of less than 1/8th the maximum tolerated dose.

#### **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:

- **Develop KZR-616 in multiple autoimmune indications.** We believe that KZR-616 has the potential to treat a wide range of immunemediated diseases. We are conducting Phase 2 trials across three indications of high unmet need. Assuming positive results from these trials, we intend to explore registration-enabling trials in each indication.
- **Develop KZR-261 in oncology.** We believe KZR-261 has the potential to be a first-in-class therapeutic modulating the protein secretion pathway and the Sec61 translocon. KZR-261 has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies by inhibiting multiple pathways for tumor growth and survival.
- Expand our pipeline of small molecule disruptors of the protein secretion pathway. We intend to continue leveraging our protein secretion platform to identify additional product candidates for the treatment of diseases with significant clinical need in oncology, immuno-oncology and inflammation. This discovery platform has the potential to yield small molecule product candidates that can selectively inhibit single proteins of interest.
- 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.

#### License Agreement with Onyx

In June 2015, we entered into the Onyx License Agreement, pursuant to which 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, to develop, manufacture and commercialize pharmaceutical products containing certain types of compounds, including KZR-616, that are selective inhibitors of 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. As partial consideration for the intellectual property rights licensed to us, we issued Onyx shares of our Series A Preferred Stock, which converted into 1,121,384 shares of our common stock upon the closing of our initial public offering on June 25, 2018.

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 our products 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

We are continuing to establish manufacturing processes for all of the components used in our product candidates to support ongoing and planned clinical trials. 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 rely on third-party contract manufacturing organizations, or CMOs, to manufacture all of our raw materials, intermediaries, active pharmaceutical ingredients, or API, and finished drug product for our clinical trials. We require that our CMOs produce API and finished drug product used in our clinical trials in accordance with cGMP and all other applicable laws and regulations. We also contract with additional third parties for the filling, labeling, packaging, storage and distribution of our investigational drug products. We maintain manufacturing agreements with our CMOs that include confidentiality and intellectual property provisions to protect our proprietary rights related to KZR-616 and KZR-261. We do not have long term supply agreements or arrangements for redundant supply in place; however, we believe we can identify and establish additional CMOs to manufacture our product candidates.

We may continue to rely on CMOs to develop and manufacture our products for commercial sale. Development and commercial quantities of any products 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 or KZR-261 are approved by any regulatory agency, we intend to enter into agreements with one or more CMOs for their commercial production.

We are currently administering KZR-616 as a lyophilized product candidate, meaning it is freeze-dried and must be reconstituted with water prior to delivery to a patient. In our clinical trials, KZR-616 is reconstituted in the hospital pharmacy prior to patient administration. In December 2021, we introduced at-home self-administration of KZR-616 for patients in the PRESIDIO OLE study. We intend that if approved and commercialized, KZR-616 will be self-administered by patients using the sterile vial-adaptor device.

#### 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, a Sanofi company, is engaged in preclinical research focused on the discovery of orally bioavailable and selective inhibitors of the immunoproteasome. In addition, Merck KgaA was evaluating an LMP7-selective inhibitor in a Phase 1 clinical trial in Multiple Myeloma, which was terminated in 2021.

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. Additionally, there are two drugs recently approved by the FDA for the treatment of lupus nephritis: Benlysta® (belimumab), an anti-BAFF monoclonal antibody from GlaxoSmithKline is approved for the treatment of moderate to severe lupus and lupus nephritis; and Lupkynis™ (voclosporin), a calcineurin inhibitor from Aurinia Pharmaceuticals, is approved for the treatment of active lupus nephritis, in each case in combination with a background immunosuppressive therapy regimen.

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 Saphnelo $^{TM}$  (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 Olumiant® (evobrutinib), under evaluation by Merck KgaA.

In active, proliferative lupus nephritis, other companies are developing novel agents to add to the standard induction regimens, such as Saphnelo™ (anifrolumab), the B-cell depleting agent Gazyva® (obinutuzimab) from Roche.

#### **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, formulations, and salt and polymorph related claims.

In total, our patent portfolio, including patents licensed from Onyx, comprises more than 10 different patent families, filed in various jurisdictions worldwide, including families directed to composition of matter for selective immunoproteasome inhibitors and protein secretion inhibitors. 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 2037. Our patent portfolio is outlined below:

KP-00-001—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.

KP-00-002—composition of matter patent covering selective immunoproteasome inhibitors, including selective LMP7 inhibitors and dual LMP7/LMP2 inhibitors. We have issued patents in numerous jurisdictions, including the United States, Europe, Eurasia, Australia, China, Columbia, Indonesia, Jordan, Japan, Lebanon, Mexico, Saudi Arabia, Singapore and Taiwan. 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.

KP-00-003—composition of matter patent covering selective immunoproteasome inhibitors of the LMP2 subunit. We have issued patents in numerous jurisdictions, including the United States, Europe, Eurasia, Australia, China, Mexico and Singapore. The 20-year term of this family is March 2034, absent any patent term extensions available.

KP-00-004— patent application pending in numerous jurisdictions, directed to process for preparing KZR-616. We have an issued patent in the United States. The 20-year term for this family is June 2037, absent any patent term extensions available.

KP-00-005— patent application pending in numerous jurisdictions, directed to various salts and polymorphs of KZR-616, including the clinical salt form. We have an issued patent in the United States. The 20-year term for this family is June 2037, absent any patent term extensions available.

KP-00-006 and KP-00-007— 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, 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.

KP-00-008 – patent application directed to formulations of KZR-616 is pending, with no issued patents yet. The 20-year term of this family is expected to be October 2039, absent any patent term extensions available.

We continue to file applications for new methods of treatment, clinical protocols, and other uses in view of results from ongoing drug discovery and development 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 a pending application around protein secretion inhibitors directed to a chemical scaffold developed in collaboration with the Taunton Lab at UCSF. There are no issued patents yet, but the 20-year term of this family is expected to be March 2039, absent any patent term extensions available.

KP-01-002 – composition of matter patent application pending directed to protein secretion modulators and covering Kezar's current clinical candidate KZR-261 as a tumor therapeutic, with no issued patents yet. The 20-year term of this family is expected to be March 2039, absent any patent term extensions available.

KP-01-004— composition of matter patent application directed to a protein secretion modulator chemical scaffold developed by Kezar. There are no issued patents yet, but the 20-year term of this family is expected to be February 2040, absent any patent term extensions available.

We continue to file applications for new composition of matter for other protein secretion modulators and new methods of treatment, in view of results from ongoing drug discovery and development efforts.

#### 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.

### **United States Government Regulation**

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act 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 new drug applications, or 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 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 GCP 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 application. Some nonclinical testing may continue even after the IND application is submitted. An IND application 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 application 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 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 ODD 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. ODD must be requested before submitting an NDA. ODD 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 ODD, 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 Drug Supply Chain Security Act 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, and the civil monetary penalties prohibit 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, or attempting to execute 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, including covered entities, business associates and their covered subcontractors, 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), 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.

#### Privacy and Data Security

In the ordinary course of our business, we may process personal data. Accordingly, we are, or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. Such obligations may include, without limitation, the Federal Trade Commission Act, the Telephone Consumer Protection Act of 1991the California Consumer Privacy Act of 2018, the European Union's General Data Protection Regulation 2016/679, or EU GDPR, the EU GDPR as it forms part of United Kingdom ("UK") law by virtue of section 3 of the European Union (Withdrawal) Act 2018, or UK GDPR, and the ePrivacy Directive. In addition, several states within the United States have enacted or proposed data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado Privacy Act.

European data privacy and security laws (including the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. For example, the EU GDPR applies to any company established in the European Economic Area, or EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authorities and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances.

See the section titled "Risk Factors – Risks Related to Our Business Operations, Employee Matters and Managing Growth" for additional information about the laws and regulations to which we are or may become subject and about the risks to our business associated with such laws and regulations.

## 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. There have been executive, judicial and Congressional challenges to certain aspects of the PPACA. For Example, President Trump signed several 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 considered legislation to repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, several 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 taxbased 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." Further, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. 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 June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the PPACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is possible the PPACA will be subject to judicial or congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration 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 2031 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. Additionally, on March 11, 2021,

President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. 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 used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule and guidance in September 2020, implementing a portion of the importation executive order providing pathway for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. 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 Medicare Access and CHIP Reauthorization Act of 2015, which introduced a merit based incentive bonus program for Medicare physicians, also referred to as the Quality Payment Program, 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. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. We cannot predict the full impact 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.

We expect additional healthcare reform initiatives to be adopted in the future. We also expect these initiatives to increase pressure on drug pricing. Further, it is possible that additional governmental action is taken in response to the evolving effects of the ongoing COVID-19 pandemic.

#### 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 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.

#### **Environmental, Social and Governance**

We are highly committed to policies and practices focused on environmental, social and corporate governance, or ESG, positively impacting our social community and maintaining and cultivating good corporate governance. By focusing on such ESG policies and practices, we believe we can affect a meaningful and positive change in our community and maintain an open, collaborative and positive corporate culture. We are developing KZR-616 as a potential therapeutic for autoimmune disorders that disproportionately impact underserved communities and in orphan indications where there is a high unmet medical need.

To ensure our ongoing success, we are committed to promoting and maintaining an inclusive, high-performing culture where all team members embrace and leverage each other's talents and backgrounds. Our commitment to diversity is articulated in our values and reflected in every part of the organization, including an employee led Diversity, Equity & Inclusion council. We are proud to actively support mentoring programs and internships for students in underserved communities as well as those interested in pursuing degrees in science and technology.

Kezar is committed to environmentally responsible operations, which includes using natural resources wisely and considering our overall impact on the environment. We conduct our operations in a single office and laboratory space to minimize waste and use of energy and water. We take steps to reduce waste streams and ensure proper treatment of both hazardous and non-hazardous materials.

We are committed to conducting our business ethically and helping ensure that we comply with the laws and regulations that govern our business and industry in all markets in which we operate. Our employees receive training on our Code of Business Conduct and Ethics and other compliance measures. Additional corporate governance measures are discussed in our proxy statement.

# **Employees and Human Capital Resources**

As of December 31, 2021, we had 56 full-time employees, 42 of whom were primarily engaged in research and development activities and 14 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. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of equity-based compensation awards and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

#### **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. Such risks may be amplified by the ongoing COVID-19 pandemic and its potential impact on our business and the global economy.

#### Summary of Selected Risks Associated with our Business

Our business is subject to numerous risks and uncertainties, including those discussed at length in the section titled "Risk Factors." These risks include, among others, the following:

- 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.
- We have a limited operating history and have never generated 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 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. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary
  rights.
- The terms of the Loan Agreement with Oxford Finance LLC place restrictions on our operating and financial flexibility.
- The ongoing COVID-19 pandemic may cause disruptions to our business and negatively affect our ability to enroll and conduct our clinical trials.
- Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of KZR-616, KZR-261 and any future product candidates.
- Success in preclinical studies or earlier clinical trials may not be indicative of future clinical trial results, and we cannot assure you that any clinical trials will lead to results sufficient for the necessary regulatory approvals.
- Clinical trials are very expensive, time consuming and difficult to design and implement.
- We may encounter substantial delays or difficulties in enrolling and retaining patients in our 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.
- 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.
- 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.
- 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.
- Even if our 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.
- · We face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.

- Our relationships with customers, physicians, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, transparency 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.
- We rely on third parties to manufacture clinical supplies of our product candidates and to conduct, supervise and monitor our preclinical studies and clinical trials. If those third parties perform in an unsatisfactory manner, it may harm our business.
- Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we
  breach our exclusive license agreement with Onyx Therapeutics, Inc., we could lose the ability to continue the development and
  commercialization of KZR-616.
- If we are unable to obtain and maintain patent protection for KZR-616 and KZR-261, if the scope of patent protection 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.
- Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.
- 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.
- If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports, about our business or our market, our stock price and trading volume could decline.
- 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.

## 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 \$54.6 million, \$41.7 million and \$35.1 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, we had an accumulated deficit of \$180.7 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 and KZR-261 and future product candidates from our protein secretion program;
- seek to discover and develop additional product candidates, including preclinical studies and clinical trials for such product candidates;
- maintain, protect and expand our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- seek marketing approvals for KZR-616, KZR-261 and any future product candidates that successfully complete clinical trials;
- 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;
- · implement operational, financial, management and compliance systems; and
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel.

In addition, because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to accurately predict the timing or amount of increased expenses and 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 initiation, enrollment or 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 necessary to obtain marketing approval, we anticipate incurring significant costs associated with launching and commercializing KZR-616, KZR-261 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 the 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 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 conducting preclinical and clinical development of KZR-616 and KZR-261, as well as research and discovery activities of future product candidates under our protein secretion program. 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 of our product candidates. 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, KZR-261 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, KZR-261 and any future product candidates;
- obtaining regulatory approvals for KZR-616, KZR-261 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 administering 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, KZR-261 and any future product candidates, if approved;
- obtaining market acceptance, if and when approved, of KZR-616, KZR-261 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 comparable foreign 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.

As of December 31, 2021, we had cash, cash equivalents and marketable securities of \$208.4 million. In November 2021, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance providing us with up to \$50.0 million of borrowing capacity across five potential tranches. The initial tranche of \$10.0 million was funded at closing of the Loan Agreement. We believe that our cash, cash equivalents and marketable securities as of December 31, 2021 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, including as a result of the COVID-19 pandemic, 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. If disruption from COVID-19 persists and deepens and global economic conditions worsen, we could experience an inability to access additional capital or engage in strategic transactions on terms reasonable to us, or at all.

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, KZR-261 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, KZR-261 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. In December 2021, we filed an automatic shelf registration statement on Form S-3ASR (Registration No. 333-261774) that allows us to sell up to an aggregate of \$200 million of our securities, which includes a prospectus for an at-the-market offering program, or ATM program. As of March 15, 2022, approximately \$192.4 million remains available under the automatic shelf registration statement. 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. For example, our obligations under the Loan Agreement are secured by a security interest in all of our assets, other than our intellectual property which is subject to a negative pledge. In addition, the Loan Agreement contains customary covenants that, subject to specific exceptions, restrict our ability to, among other things, declare dividends or redeem or repurchase equity interests, incur additional liens, make loans and investments, incur additional indebtedness,

engage in mergers, acquisitions and asset sales, transact with affiliates, undergo a change in control, add or change business locations, or engage in businesses that are not related to its existing business.

In addition, 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.

The terms of the Loan Agreement with Oxford Finance place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In November 2021, we entered into the Loan Agreement with Oxford Finance, providing us with up to \$50.0 million of borrowing capacity across five potential tranches. The initial tranche of \$10.0 million was funded at closing of the Loan Agreement. Our overall leverage and certain obligations and affirmative and negative covenants contained in the related documentation could adversely affect our financial health and business and future operations by limiting our ability to, among other things, satisfy our obligations under the Loan Agreement, refinance our debt on terms acceptable to us or at all, plan for and adjust to changing business, industry and market conditions, use our available cash flow to fund future acquisitions and make dividend payments, and obtain additional financing for working capital, to fund growth or for general corporate purposes, even when necessary to maintain adequate liquidity.

If we default under the Loan Agreement, Oxford Finance may accelerate all of our repayment obligations and exercise all of their rights and remedies under the Loan Agreement and applicable law, potentially requiring us to renegotiate our agreement on terms less favorable to us. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Oxford Finance could declare a default upon the occurrence of an event of default, including events that they interpret as a material adverse change as defined in the Loan Agreement, payment defaults or breaches of certain affirmative and negative covenants, thereby requiring us to repay the loan immediately. Any declaration by Oxford Finance of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. Additionally, if we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

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.

We acquired rights to KZR-616, pursuant to an exclusive 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 KZR-616. If these payments become due, we may not have sufficient funds available to meet our obligations and our development efforts may be harmed.

# The ongoing COVID-19 pandemic may cause disruptions to our business and may impact our ability to access capital.

The ongoing COVID-19 pandemic has led to the implementation of public health safety measures and restrictions, as well as adverse impacts on healthcare facilities and hospitals across the United States and in other countries where we conduct our clinical trials. While we are not experiencing any material financial impacts at this time, the overall disruption of global healthcare systems, delays encountered with regulatory authorities and the other risks and uncertainties associated with the pandemic could materially and adversely affect our business operations, operating results and financial condition, the magnitude of which will depend on the length and severity of the restrictions, as well as the duration of the COVID-19 pandemic and the outcome of vaccination measures.

Public health safety measures implemented as a result of COVID-19 may adversely impact our business operations, as well as the contract research organizations, or CROs, that support our clinical trials. In response to the ongoing COVID-19 pandemic, we and our CROs have taken measures to implement remote and virtual approaches, such as home health services and remote patient monitoring, where appropriate and possible, to maintain patient safety and trial continuity, to reduce travel to healthcare facilities and to preserve the integrity of our clinical trials. The COVID-19 pandemic may also negatively impact our ability to interact with ethics committees and other regulatory authorities due to limitations in employee resources, access to clinical sites or otherwise.

The spread of COVID-19 has caused a broad impact globally and may materially affect us economically. The global pandemic of COVID-19 continues to evolve. While the United States has been lifting its public health restrictions, any new developments that prolong or increase the severity of the pandemic, including the emergence of variants, could result in disruptions to global financial

markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. The extent to which it impacts our business, clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the efficacy of vaccines and the evolution of viral variations and mutations, as well as travel restrictions, social distancing requirements and business restrictions in the United States and other countries. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

# Our ability to use net operating losses and certain other tax attributes to offset future taxable income may be subject to limitation.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Our NOLs generated in tax years beginning on or prior to December 31, 2017 are permitted to be carried forward for only 20 years under applicable U.S. tax law. Our federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020 is subject to certain limitations. It is uncertain if and to what extent various states will conform to federal law with respect to the limitations on the use of NOLs.

In addition, under Section 382 and Section 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," its ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points (by value) over their lowest ownership percentage over a rolling three-year period. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership (some of which are outside our control). As a result, if we earn net taxable income, our ability to use our prechange 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.

Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations.

# Changes in tax laws or regulations could materially adversely affect our company.

The tax regimes we are subject to or operate under, including income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. For example, the 2017 Tax Cuts and Jobs Act, or the Tax Act, together with the CARES Act that was enacted March 27, 2020, made broad and complex changes to the U.S. tax code, including changes to U.S. federal tax rates, additional limitations on the deductibility of interest, both positive and negative changes to the utilization of future net operating loss, or NOL, carryforwards, and allowing for the expensing of certain capital expenditures. Recently, in the United States, Congress and the Biden administration proposed legislation (which has not yet been enacted) to make various tax law changes, including to increase U.S. taxation of international business operations and impose a global minimum tax. These proposals, recommendations and enactments include changes to the existing framework in respect of income taxes that could apply to our business.

## 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, KZR-261 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. We have not obtained regulatory approval for any product candidate, and it is possible that neither our current product candidates, 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, KZR-261 or any future product candidates in the United States or abroad until we receive regulatory approval from the FDA or the applicable foreign regulatory authority.

Prior to obtaining approval to commercialize our product candidates 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 clinical trials and preclinical

studies can be interpreted in different ways. Even if we believe the clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign 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 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 product candidates in development, only a small percentage are successfully approved by the FDA or a comparable foreign regulatory authority 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 limited financial and management resources in the development of KZR-616, KZR-261 and any future product candidates. Our business is dependent on our ability to successfully complete development of, obtain regulatory approval for, and, if approved, successfully commercialize KZR-616 and KZR-261 in a timely manner. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities.

Even if we eventually complete clinical testing and receive approval of a new drug application, or NDA, or foreign marketing application for KZR-616, KZR-261 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 than 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. In addition, due to the ongoing COVID-19 pandemic, we could also experience delays in the timing of our interactions with regulatory authorities due to absenteeism by governmental employees, inability to conduct planned physical inspections related to regulatory approval, or the diversion of regulatory authority efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay anticipated approval decisions and otherwise delay or limit our ability to make planned regulatory submissions or obtain new product approvals.

Even if we receive regulatory approval to market any of our product candidates, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Furthermore, even if we obtain regulatory approval for any of our 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, KZR-261 and any future product candidates, we may not be able to generate sufficient revenue to continue our business.

If we are not successful in developing KZR-616 and KZR-261, or discovering and developing additional product candidates, our ability to expand our pipeline and achieve our strategic objectives would be impaired.

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 immune-mediated and oncologic disorders. We are conducting research and discovery efforts targeting the protein secretion pathway and, in October 2021, we initiated a Phase 1 clinical trial of KZR-261, our first clinical candidate for development in oncology. However, our current and future research programs may fail to yield product candidates with acceptable pharmaceutical properties for clinical development. 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. Efforts to discover and develop new product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. If we are unsuccessful in building our pipeline beyond our current product candidates, our ability to generate product revenue would be impaired, which could significantly harm our financial position and adversely affect the trading price of our common stock.

If the market opportunities for KZR-616 and KZR-261 are smaller than we believe they are, our business may suffer.

We currently focus our drug development of KZR-616 on treatments of immune-mediated 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 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. Our Phase 1 trial of KZR-261 is designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, and we have not yet selected the tumor types or patient populations for the next stages of clinical development. The number of patients for either product candidate 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.

Due to the significant resources required for research and development, we must prioritize development of certain product candidates. We may expend our limited resources to pursue particular drug candidates and fail to capitalize on other product candidates that may be more profitable or for which there may be a greater likelihood of success.

In addition to our clinical trials underway for KZR-616 and KZR-261, we are conducting research and discovery efforts targeting the protein secretion pathway. The development of these product candidates requires significant capital investment. Due to the significant resources required for the development of KZR-616, KZR-261 and any future product candidates, we must focus our research and development efforts on specific indications and decide which product candidates to pursue and advance. Our decisions concerning the allocation of research, development, management, and financial resources toward particular product candidates may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we do not accurately evaluate the viability and commercial potential of our product candidates, we may fail to capitalize on profitable market opportunities, forego or delay opportunities to pursue other product candidates or other indications that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidates.

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 may include entering into product development collaborations, including strategic collaborations with major biotechnology or pharmaceutical companies. We cannot predict what form such a strategic collaboration might take. We face significant competition in seeking appropriate strategic collaborators, and the negotiation process can be complicated and time consuming. The COVID-19 pandemic could also impact our ability to do in-person due diligence, negotiations and other interactions to identify new development collaboration opportunities. Even if we are successful in our efforts to establish new development collaborations, the terms of such collaborations may not be favorable to us. Entering into future collaborations could subject us to a number of risks, including:

- we may be required to relinquish important rights to and control over the development and commercialization of our product candidates;
- 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.

Success in preclinical studies or earlier clinical trials may not be indicative of future clinical trial results, and we cannot assure you that any 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 trials designed to test efficacy 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.

## 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. The clinical trial process is expensive, time consuming, and subject to uncertainty, and we estimate that the successful completion of clinical trials of our product candidates will take several years to complete. 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. We may design the inclusion and exclusion criteria for trial participation too narrowly, which would make it difficult to find and enroll patients for 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. 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 are developing KZR-616 to address several autoimmune diseases with high degrees of unmet medical need, including lupus nephritis, dermatomyositis and polymyositis, and in the future may evaluate other rare immune-mediated disease indications. If the actual number of patients with these disorders is smaller than we anticipate, or if these patients are unwilling to participate in a clinical trial, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our product candidates. In October 2021, we initiated a Phase 1 clinical trial studying KZR-261 for the treatment of solid tumors in oncology, for which there is substantial competition for participation in clinical trials. 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. For example, the impact of public health epidemics, such as the COVID-19 pandemic, or geopolitical tensions, such as Russia's recent incursion into Ukraine, may delay or prevent patients from enrolling or from receiving treatment in accordance with the protocol and the required timelines, which could delay our clinical trials, or prevent us from completing our clinical trials at all. Any inability to timely and successfully complete clinical development will increase our costs, slow our development plans and impair our ability to generate revenue from our product candidates. In addition, we may be reliant on CROs and clinical trials sites to ensure proper and timely conduct of our clinical trials and, while we intend to enter into agreements governing their services, we will be limited in o

## 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 a comparable foreign 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. 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 cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. For example, the implementation of public health safety measures and the demands on our healthcare system relating to the COVID-19 pandemic have impacted our clinical development timelines and previously anticipated data release milestones for KZR-616. Moreover, circumstances may arise that could result in suspending or terminating our ongoing clinical trials. As an example, some patients included in the MISSION Phase 2 clinical trial are located in Ukraine and Russia. The escalation of tensions in the region, including Russia's February 2022 incursion into Ukraine and the resulting imposition of economic and other sanctions by the United States, European Union and many other nations on Russia, individuals in Russia, Russian businesses and the Russian central bank, could disrupt or delay our ability to conduct clinical trial activities, including the evaluation of data. Although the length and impact of any military action are highly unpredictable, clinical trial sites in Ukraine, Russia and other countries may close, and patients could be forced to evacuate or voluntarily choose to relocate far from clinical trial sites, making them unavailable for further follow-up. The closure of sites, the inability to screen and enroll new patients or any premature discontinuation of treatment by patients already enrolled in our trial could result in the need to enroll additional patients, which would be costly and could delay our anticipated timeline for the completion of the trial. Any inability to timely and successfully complete preclinical and clinical development will increase our costs, slow our development plans and impair our ability to generate revenue from our product candidates.

We may experience numerous unforeseen events that may prevent the timely and successful completion of our clinical trials, or result in the termination of such clinical trials prior to their completion, including:

- allocation of hospital and healthcare resources to focus on care and treatment of patients with COVID-19 and away from conducting clinical trials;
- interruptions in our business as a result of the COVID-19 outbreak, such as restrictions on travel and meetings with clinical trial sites and investigators, as well as potential disruptions in our product supply chain;
- failure to recruit suitable patients to participate in a clinical trial, enrollment in these clinical trials may be slower than we anticipate, and participants may drop out during the course of these trials at a higher rate than we anticipate or fail to return for post-treatment follow-up because of the COVID-19 pandemic;
- · delays in reaching a consensus with the FDA and comparable foreign regulatory authorities on the design of our clinical trials;
- the number of patients required for clinical trials to produce statistically meaningful data may be larger than we anticipate;

- delays in manufacturing, testing, releasing, validating and shipping stable quantities of our product candidates for our clinical trial sites;
- the costs of clinical trials of our product candidates may be greater than we anticipate;
- regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site, or may otherwise suspend our clinical trials at any time if it appears we are or our collaborators are failing to conduct a trial in accordance with regulatory requirements;
- the perceived risk by investigators, patients or IRBs of participating in a clinical trial of KZR-616, a selective immunoproteasome inhibitor, due to the effects of COVID-19 and/or KZR-616 on the immune system;
- delays in identifying and recruiting suitable clinical investigators or reaching agreement on acceptable terms with prospective clinical trial sites;
- 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;
- failure to perform our clinical trials in accordance with current Good Clinical Practice, or cGCP, or regulations required by the FDA or comparable foreign regulatory authorities;
- changes in regulatory requirements and guidance or other unforeseen regulatory developments that require amending or submitting new clinical protocols;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; or
- business interruptions resulting from geo-political actions, such as Russia's recent incursion into Ukraine, war, terrorism, natural disasters or public health epidemics.

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. 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.

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 held liable for harm causes to patients; or
- experience damage to our reputation.

Further, we, the FDA, comparable foreign 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 cGCP, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our investigational new drug applications, 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.

Our product candidates have been involved, and may be involved in the future, in investigator-initiated clinical trials, and we have limited or no control over the conduct of such trials.

KZR-616 has been involved in an investigator-initiated clinical trial, and our product candidates may be involved in investigator-initiated clinical trials in the future. Investigator-initiated clinical trials pose similar risks as those set forth elsewhere in this "Risk Factor" section relating to our own internal clinical trials. However, while investigator-initiated clinical trials may provide us with clinical data that can inform our development strategy, we generally have less control over the conduct and design of such trials. Because we are not the sponsors of investigator-initiated clinical trials, we do not control the protocols, administration or conduct of these trials, including follow-up with patients and the ongoing collection of data. Negative results in investigator-initiated clinical trials could have a material adverse effect on our business and prospects and the perception of our product candidates.

# The ongoing COVID-19 pandemic could negatively affect our ability to enroll and conduct our clinical trials.

Our clinical trials have been and may continue to be affected by the COVID-19 pandemic. As a result of the implementation of public health safety measures and the demands on the global healthcare system relating to COVID-19, we have experienced delays in the clinical development timelines for our product candidates. Clinical site initiation and patient enrollment has been delayed due to prioritizing hospital resources for the treatment of patients with COVID-19. In particular, outside of the United States, we have experienced delays in receiving approval from local regulatory authorities to initiate our clinical trials in certain countries, and local regulatory authorities have adopted different risk limiting measures that we are required to meet to conduct our clinical trials. In addition, the patients in our clinical trials may not be able to comply with clinical trial protocols if public safety measures impede travel and mobility or interrupt healthcare services. We may also experience the following adverse impacts:

- delays or difficulties enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel;
- the perceived risk by investigators, patients or institutional review boards, or IRBs, of participating in a clinical trial of KZR-616, a selective immunoproteasome inhibitor, due to the effects of COVID-19 and/or KZR-616 on the immune system;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- non-compliance or withdrawal of consent by patients due to limitations on travel to clinical trial sites or other reasons; and
- interruptions in clinical drug supply due delays in manufacturing, drug substance or drug product shipments from contract manufacturing organizations, or CMOs, to depot centers and from depot centers to clinical trial sites.

For our clinical trials that are being conducted at sites outside the United States, particularly in countries which are experiencing heightened impact from COVID-19, in addition to the risks listed above, we may also experience the following adverse impacts:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product and placebo used in our clinical trials;
- changes in local regulations as part of a response to the coronavirus outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether; and
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

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 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, particularly from our open-label studies. 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. Preliminary or top-line data may include, for example, data regarding a small percentage of the patients enrolled in a clinical trial, and such preliminary data should not be viewed as an indication, belief or guarantee that other patients enrolled in such clinical trial will achieve similar results or that the preliminary results from such patients will be maintained. As a result, interim and preliminary data may not be statistically significant and should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data may cause the trading price of our common stock to fluctuate significantly and could significantly harm our business prospects.

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, discomforts and other adverse events, 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, KZR-261 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.

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.

In October 2020, we received orphan drug designations in both polymyositis and dermatomyositis for KZR-616 in the United States. Both rare diseases are autoimmune inflammatory myopathies that are chronic and debilitating diseases characterized by marked morbidity and mortality. We intend to pursue orphan drug designation for KZR-616 in other orphan immune-mediated disease indications. Obtaining orphan drug designation in additional indications and other jurisdictions may be difficult, and we may not be successful in doing so. The exclusivity for our orphan drug designations, and for any other designations that we may obtain in the future, 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.

Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval for our 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, KZR-261 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, KZR-261 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, KZR-261 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 our product candidates will be harmed and our business, financial condition, results of operations and prospects could be harmed. Due to the ongoing COVID-19 pandemic, it is possible that we could experience delays in the timing of our interactions with regulatory authorities due to absenteeism by governmental employees, inability to conduct planned physical inspections related to regulatory approval, or the diversion of regulatory authority efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay anticipated approval decisions and otherwise delay or limit our ability to make planned regulatory submissions or obtain new product approvals.

# Even if we obtain regulatory approval for any of our product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain regulatory approvals for our 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 our 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 comparable foreign 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 any of our 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 our product candidates and harm our business, financial condition, results of operations and prospects.

The FDA's and comparable foreign regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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.

Even if our 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 our 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 product revenue and may not become profitable. The degree of market acceptance of KZR-616, KZR-261 and 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, if we enter into a strategic collaboration regarding any of our product candidates, our rights to receive milestone payments and royalties related to such product candidates will depend on our collaborators' abilities to achieve market acceptance of those product candidates.

KZR-616 is being developed as a lyophilized formulation which could adversely affect market acceptance if patients are required to reconstitute KZR-616 themselves prior to injection.

We are developing KZR-616 as a lyophilized product candidate, meaning that it will be freeze-dried and must be reconstituted with water prior to patient administration. While lyophilized products are common in the drug industry, this method for administering KZR-616 could adversely affect market acceptance and make it more difficult to conduct clinical trials of KZR-616. In our current trials, KZR-616 is reconstituted in the hospital pharmacy prior to patient administration. Beginning with our PRESIDIO open-label extension study, patients will be able to reconstitute KZR-616 at home prior to injection using a sterile vial-adaptor device.

Separately, we are conducting feasibility studies and engineering runs for 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. For example, 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 would need to seek approval for KZR-616 via the vial-adaptor system, which could require additional bio-equivalence or efficacy clinical trials in order to later transition to the dual-chamber system. If delivered by a self-administered dual-chamber system, KZR-616 may also 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 would 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 at the FDA based on its primary mode of action as a drug, the FDA could disagree.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing such 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 our 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.

# If we seek to commercialize our product candidates outside of the United States, a variety of risks associated with international operations could harm our business.

If we seek to commercialize our product candidates outside of the United States, we expect that we will be subject to additional risks 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, war, terrorism, natural disasters and public health epidemics.

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.

# 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 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 are 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.

Coverage and adequate reimbursement may not be available for KZR-616, KZR-261 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, KZR-261 or any future product candidates that we develop.

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 our product candidates in clinical trials, both within and outside of the United States, 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, transparency 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, including 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, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program, or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, which
  impose certain requirements relating to the privacy, security and transmission of individually identifiable health information on health plans,
  health care clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates and their
  subcontractors 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), 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 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.

# 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.

Since its passage, there have been varied executive, judicial and Congressional challenges to certain provisions of the PPACA. In addition, Congress has considered, and may consider in the future, legislation to repeal or repeal and replace all or part of the PPACA. While Congress has not passed any comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the PPACA have been signed into law. On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the PPACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and 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, will remain in effect through 2031 unless additional congressional action is taken. COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. 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 introduced a merit-based incentive bonus program for Medicare physicians, also referred to as the Quality Payment Program. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, the full impact of the introduction of the Medicare Quality Payment Program on overall physician reimbursement remains unclear.

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. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. 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. It is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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

# We will rely on third parties to manufacture clinical and commercial supplies of KZR-616, KZR-261 and any future product candidates.

We do not own or operate facilities for drug manufacturing, testing, storage or distribution. We are dependent on third parties to manufacture the clinical supplies of our product candidates. Any significant delay in the supply of a product candidate or raw material components for an ongoing clinical trial due to the need to replace a third-party CMO could considerably delay the completion of our clinical trials. In particular, our CMOs may experience business interruptions as a result of shelter-in-place orders or other impacts due to the ongoing COVID-19 pandemic, which would potentially impact our product supply chains and clinical trials. We are completely dependent on our CMOs for compliance with cGMP for manufacture of both active drug substances and finished drug products. If our CMOs cannot successfully manufacture active drug substances and finished drug product that conform to our specifications and the strict regulatory requirements of the FDA and comparable foreign regulatory authorities, we will not be able to secure or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. Our ability to audit the facilities of our CMOs and other vendors will be interrupted by COVID-19 pandemic-related travel restrictions. 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 timelines and ability to develop, obtain regulatory approval for or market our product candidates, if approved.

The facilities used by our CMOs to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA for any of our product candidates. We also expect to rely on third-party manufacturers to supply us with sufficient quantities of our product candidates to be used, if approved, for commercialization.

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 and other inspections by the FDA or comparable foreign 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.

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 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. 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 and good clinical practices, or GCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities in the form of International Council for Harmonisation guidelines for any of our product candidates that are in preclinical and clinical development, respectively. The regulatory authorities enforce GCP 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 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 GCP, 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, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our reliance on third parties to conduct clinical trials results 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. Our CROs and other third parties may experience business interruptions as a result of shelter-in-place orders or other impacts due to the ongoing COVID-19 pandemic. In addition, such parties may:

have staffing difficulties;

- fail to comply with contractual obligations;
- not devote sufficient time and resources to our clinical trials;
- experience regulatory compliance issues; or
- undergo changes in priorities or become financially distressed.

These factors may materially adversely affect the timelines of 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, the product candidate being developed. As a result, our financial results and commercial prospects would be harmed, our costs could increase, and our ability to generate revenue from the product candidate could be delayed. 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 compete with recruitment of our clinical trials.

If our relationship with any of these CROs terminates, we may be delayed in entering into new arrangements with alternative CROs or unable to do so on commercially reasonable terms. Changing CROs during an ongoing clinical trial involves substantial cost, 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 our product candidates.

# **Risks Related to 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, we could lose the ability to continue the development and commercialization of KZR-616.

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 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, to develop, manufacture and commercialize certain types of compounds, including KZR-616, that are selective inhibitors of the immunoproteasome for any and all uses, other than those related to the diagnosis or treatment in humans of cancerous or precancerous diseases or conditions, including those related to hematological diseases 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 or treatment in humans of cancerous or pre-cancerous diseases or conditions, including those related to hematological diseases or conditions, and also has the rights to transfer these rights to a third-party. If Onyx or its licensee develops and commercializes any of the licensed compounds in cancer or pre-cancerous indications that are commercially interchangeable with our product candidates, including KZR-616, sales by Onyx or its licensee of such compounds for cancer and pre-cancerous indications could result in the threat of off-label use 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.

If we are unable to obtain adequate protection for our proprietary know-how or obtain and maintain patent protection for KZR-616, KZR-261 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, KZR-261 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 research 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 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 certain patents and patent applications 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 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 clinical trials or regulatory approvals, the period of time during which we could market our product candidates under patent protection would 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, KZR-261 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. 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 the initial filing. 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 until such publication dates have passed. 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 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, KZR-261 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. Upon the expiration of patent protection for KZR-616, KZR-261 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 our product 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 patents 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 is structurally 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 our patents is not sufficiently broad to impede such competition, or if the breadth, strength or term (including any extensions or adjustments) of protection provided by our patents is successfully challenged, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

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 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 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

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 and KZR-261, 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.

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, KZR-261 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, KZR-261 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, KZR-261 or 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 and protein secretion 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 our 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 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 our 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.

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

In addition to seeking patent protection for 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.

# 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 develop and manufacture KZR-616 and KZR-261, and if we collaborate with third parties for the development of our research programs or product candidates, we must, at times, share trade secrets with them. We may also conduct collaborative research and development programs that may require us to share trade secrets and proprietary know how. We seek to protect our proprietary information by entering into agreements containing confidentiality obligations and ownership provisions relating to intellectual property prior to disclosing proprietary information or beginning research projects with third party collaborators. 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, sharing 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, the unauthorized disclosure or use of our confidential information could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees, investigators, 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, advisors, employees, investigators, 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.

# 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, KZR-261 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.

# 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 prevent us from fully exploiting our product candidates or technologies.

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

We are highly dependent on the services of our executive officers, 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 the services of our Chief Executive Officer, John Fowler, our President and Chief Scientific Officer, Christopher Kirk, Ph.D., and our Chief Medical Officer, Noreen Henig, M.D. Each of them may terminate their employment with us at any time. The loss of the services of any 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. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. 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. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

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

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, medical affairs, 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.

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data, Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors). In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR and the United Kingdom's GDPR, or UK GDPR impose strict requirements for processing the personal data of individuals located, respectively within the European Economic Area, or EEA and the United Kingdom, or UK. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to our processing of their personal data. Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the EEA, such as the United States, which the European Commission does not consider to provide an adequate level of data privacy and security. The European Commission released a set of "Standard Contractual Clauses" that are designed to be a valid mechanism by which entities can transfer personal data out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. Currently, these Standard Contractual clauses are a valid mechanism to transfer personal data outside of the EEA. The Standard Contractual Clauses, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. Moreover, due to potential legal challenges, there exists some uncertainty regarding whether the Standard Contractual Clauses will remain a valid mechanism for transfers of personal data out of the EEA. In addition, laws in Switzerland and the UK similarly restrict transfers of personal data outside of those jurisdictions to countries such as the United States of America that do not provide an adequate level of personal data protection. In addition to European restrictions on cross-border transfers of personal data, other jurisdictions have enacted or are considering similar cross-border personal data transfer laws and local personal data residency laws, any of which could increase the cost and complexity of doing business. If we cannot implement a valid compliance mechanism for cross-border privacy and security transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or elsewhere. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to European and other data privacy and security laws; or requiring us to increase our personal data processing capabilities in Europe and/or elsewhere at significant expense.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations which could impact our compliance posture. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

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

In the ordinary course of our business, we may process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets. We may rely upon third parties (such as service providers) for our data processing-related activities. We may share or receive sensitive data with or from third parties. We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services.

In addition, in response to the COVID-19 pandemic, we enabled substantially all of our employees to work remotely, which poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections outside our premises. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

Any of the previously identified or similar threats could cause a security incident. A security incident could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data. A security incident could disrupt our ability (and that of third parties upon whom we rely) to conduct our busines. 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. We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and data. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. S

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Additionally, we cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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 comparable foreign 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 comparable foreign 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. Further, because of the work-from-home policies we implemented due to COVID-19, information that is normally protected, including company confidential information, may be less secure. If 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 onetime 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 and Other General Matters

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 price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and

other adverse effects or developments relating to the ongoing COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance. 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, KZR-261 and any future product candidates;
- the clinical or commercial success of competitive drugs, therapies or technologies;
- regulatory or legal developments in the United States and other countries;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain and maintain patent protection for our technologies;
- failure or discontinuation of any of our clinical development or research programs;
- the recruitment or departure of key personnel;
- the level of expenses related to our product candidates and clinical development or research programs;
- our ability to discover, develop and broaden our pipeline beyond our current product candidates;
- commencement or termination of collaborations for our research and development programs;
- actual or anticipated changes in estimates as to financial results or development timelines;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- our inability to obtain or delays in manufacturing adequate supply for our clinical trials or the inability to do so at acceptable costs;
- significant lawsuits, including patent or stockholder litigation or products liability claims;
- variations in our financial results or those of companies that are perceived to be similar to us;
- announcement, expectation or completion of additional financing efforts;
- 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, including as a result of the ongoing COVID-19 pandemic and the Russian incursion into Ukraine; 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.

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.

# Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Similarly, the current conflict between Ukraine and Russia has created extreme volatility in the global capital markets and is expected to have further global

economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Inflation can adversely affect us by increasing our costs, including salary costs. Any significant increases in inflation and related increase in interest rates could have a material adverse effect on our business, results of operations and financial condition.

# Our common stock is thinly traded and our stockholders may be unable to sell their shares quickly or at market price.

Although we have had periods of high-volume daily trading in our common stock, generally our stock is thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. Our common stock price could, for example, decline significantly as a result of sales of a large number of shares of our common stock on the market without commensurate demand, as compared to a seasoned issuer that could better absorb those sales without adverse impact on its share price, or from the perception that these sales could occur.

# 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, 2021, 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 40% 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 securities or industry analysts do not publish research or reports, or publish unfavorable research or reports, about 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. Furthermore, our ability to pay cash dividends is currently restricted by the terms of the Loan Agreement. 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 these amounts 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 a "smaller reporting company," and the reduced disclosure requirements applicable to such companies may make our common stock less attractive to investors.

We are an "emerging growth company," or EGC, as defined in 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 are also a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by nonaffiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

We will continue to incur increased costs 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 costlier. 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 and smaller reporting company, 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 \(^2\)3% 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, 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 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 the following types of actions or proceedings under Delaware statutory or common law:

- 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.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

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, California 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 February 28, 2022, there were approximately 14 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.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved].

# 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 immune-mediated diseases and cancer. We believe therapies that inhibit multiple drivers of disease by targeting fundamental upstream control processes within the cell have the potential for profound therapeutic benefit in a number of difficult-to-treat diseases. To that end, we are advancing two drug development programs that harness different master regulators of cellular function: the first targets the immunoproteasome which is responsible for protein degradation in cells of the immune system and drives many key aspects of immune cell function, and the second targets the Sec61 translocon, which is located on the endoplasmic reticulum and represents the beginning of the protein secretion pathway. Targeting these fundamental regulators of cellular function offers an attractive approach to treating many diseases.

Our lead product candidate, KZR-616, is a first-in-class selective immunoproteasome inhibitor that has completed Phase 1a testing in healthy volunteers and a Phase 1b trial in patients with systemic lupus erythematosus, or SLE. We are now leveraging its broad therapeutic potential in two Phase 2 clinical trials, MISSION and PRESIDIO, treating patients with severe autoimmune diseases of high unmet medical need. The Phase 2 portion of our MISSION clinical trial is evaluating KZR-616 in patients with lupus nephritis, or LN. The PRESIDIO Phase 2 clinical trial is evaluating KZR-616 in dermatomyositis, or DM, and polymyositis, or PM, indications for which KZR-616 have been granted orphan drug designation, or ODD, by the U.S. Food and Drug Administration, or FDA. Based on Phase 1 clinical data generated to date with KZR-616, as well as preclinical data with selective immunoproteasome inhibitors, we believe that KZR-616 has the potential to address multiple chronic immune-mediated diseases.

We believe that the immunoproteasome is a validated target for the treatment of a wide variety of immune-mediated diseases given its ability to regulate multiple drivers of the inflammatory disease process. Many inflammatory disorders are currently treated one cytokine or cell type at a time, but the immunoproteasome affects a broad spectrum of immune regulators. We have seen encouraging clinical activity and biomarker data in the SLE and LN patients who received KZR-616 in the MISSION trial to date. The safety and tolerability profile of KZR-616 has been favorable and consistent with needs for a long-term therapy.

Our oncology product candidate, KZR-261, is being studied in an open-label Phase 1 clinical trial designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, as well to explore preliminary anti-tumor activity. This study will be conducted in two parts: dose escalation in subjects with locally advanced or metastatic solid malignancies, and dose expansion in subjects with selected tumor types. KZR-261 is the first clinical candidate from our novel research platform targeting the Sec61 translocon and the protein secretion pathway for the discovery and development of small molecule therapeutics for oncology and autoimmune indications. KZR-261 has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies by targeting multiple pathways driving tumor growth and survival. We believe this discovery platform has the potential to yield additional small molecule product candidates with this ability to inhibit multiple pathways as a single agent, as well as compounds designed to selectively inhibit a single secreted or transmembrane protein of interest. If successfully developed and approved, these small molecules could serve as alternatives to currently marketed biologic therapeutics to act as cytotoxic anti-cancer agents or to block the secretion of novel targets of interest in immuno-oncology or inflammation.

Since the commencement of our operations in 2015, we have devoted substantially all of 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, from public offerings of common stock and prefunded warrants to purchase common stock as described below, and debt. We acquired exclusive worldwide rights to KZR-616 and an accompanying library of similar molecules pursuant to a license agreement, or the Onyx License Agreement, with Onyx Therapeutics, Inc., or Onyx, a wholly owned subsidiary of Amgen, Inc. in June 2015. Patent coverage for KZR-616 extends to at least 2034.

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 \$54.6 million, \$41.7 million and \$35.1 million for the years ended

December 31, 2021, 2020 and 2019, respectively, and we expect to continue to incur significant losses for the foreseeable future. As of December 31, 2021, we had an accumulated deficit of \$180.7 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 and KZR-261;
- seek to discover and develop additional product candidates, including preclinical studies and clinical trials for such product candidates;
- maintain, protect and expand our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- seek marketing approvals for KZR-616, KZR-261 and any future product candidates that successfully complete clinical trials;
- 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;
- implement operational, financial, management and compliance systems; and
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel; and
- · incur additional legal, accounting and other expenses associate with operating as a public company.

# **Critical Accounting Policies 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.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements located elsewhere in this Annual Report on Form 10-K. We have listed below our critical accounting policies and estimates that we believe to have the greatest potential impact on our consolidated financial statements. Historically, our assumptions, judgments and estimates relative to our critical accounting estimates have not differed materially from actual results and no significant assumptions used have a high degree of subjectivity.

# **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 significant 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.

# **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 the tax incentive 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,					
	2021 2020			2019		
(dollars in millions)	·			(unaudited)		
Research and development expenses by program:						
KZR-616	\$	24.6	\$	18.9	\$	17.4
KZR-261		7.8		6.7		_
Protein Secretion		6.5		5.4		10.0
Total research and development expenses	\$	38.9	\$	31.0	\$	27.4

We expect our research and development expenses to increase substantially for the foreseeable future as our product candidates 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 expenses, allocated facilities costs and fees for outside consulting and professional services, including legal, human resource, information technology and audit services. Personnel expenses consist of salaries, benefits and stock-based compensation. We will incur additional expenses as we 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, cash equivalents and marketable securities.

# Interest Expense

Our interest expense consists of interest expense related to our debt facility. A portion of the interest expense is non-cash expense relating to the accretion of the final payment fees and amortization of debt discount and debt issuance costs associated with the Loan Agreement.

# **Results of Operations**

A discussion regarding our financial condition and results of operations for the year ended December 31, 2020 compared to the year ended December 31, 2019 is included in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 11, 2021.

# Comparison of the Years Ended December 31, 2021 and 2020

	Year Ended December 31,					
(dollars in millions)	2021 2020			Increase (decrease)		
Operating expenses:						
Research and development	\$	38.9	\$	31.0	\$	7.9
General and administrative		15.7		11.9		3.8
Total operating expenses		54.6		42.9		11.7
Loss from operations		(54.6)		(42.9)		(11.7)
Interest income		0.2		1.2		(1.0)
Interest expense		(0.2)		_		(0.2)
Net loss	\$	(54.6)	\$	(41.7)	\$	(12.9)

# Research and Development Expenses

Research and development expenses increased by \$7.9 million in 2021 compared to 2020. The increase was primarily due to an increase of \$2.3 million in clinical trial related costs for KZR-616, an increase of \$2.2 million in personnel related expenses due to an increase in headcount, an increase of \$1.6 million in clinical trial related start-up costs for KZR-261, an increase of \$1.4 million in drug manufacturing expenses for KZR-616, an increase of \$0.9 million in stock-based compensation, an increase of \$0.7 million in research expenses related to the protein secretion program, an increase of \$0.7 million in consulting fees driven by increased clinical development and regulatory activities, and an increase of \$0.4 million in facility-related expenses, offset by a decrease of \$2.3 million in preclinical expenses related to the IND enabling studies for KZR-261.

# General and Administrative Expenses

General and administrative expenses increased by \$3.8 million in 2021 compared to 2020. The increase was primarily due to an increase of \$1.8 million in stock-based compensation, an increase of \$1.2 million in personnel expenses due to an increase in headcount and salaries, an increase of \$0.3 million in consulting and professional service fees, an increase of \$0.2 million in directors and officers liability insurance, and an increase of \$0.3 million in facility-related expenses.

# Interest Income

Interest income decreased by \$1.0 million in 2021 compared to 2020. The decrease was primarily attributable to lower interest rates on our marketable securities.

# Interest Expense

Interest expense increased by \$0.2 million in 2021 compared to 2020. The interest expense was comprised of the contractual coupon interest expense, the amortization of the debt discount and issuance costs and the accretion of the final payment fee associated with the Loan Agreement with Oxford Finance.

# **Liquidity and Capital Resources**

#### Overview

As of December 31, 2021, we had \$62.9 million in cash and cash equivalents and \$145.5 million of marketable securities invested in a U.S. Treasury money market fund, U.S. Treasury securities, U.S. agency bonds, commercial paper and corporate debt securities. As of December 31, 2021, our cash equivalents and marketable securities had an average maturity of approximately five months and the longest maturity was eleven months.

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 \$54.6 million for the year ended December 31, 2021, and we had an accumulated deficit of \$180.7 million as of December 31, 2021.

We believe that our cash, cash equivalents and marketable securities as of December 31, 2021 will be sufficient to meet our projected operating requirements through at least the next 12 months from the date the financial statements were 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.

# At-the-Market Offering Programs

During 2021, we sold an aggregate of 9,352,359 shares of our common stock for gross proceeds of approximately \$104.1 million at a weighted average purchase price of \$11.13 per share pursuant to the at-the-market offering programs described below.

(in thousands except share and per share data)	Aggregate of shares of common stock sold in 2021	Gross proceeds		Weighted average purchase price per share	Net proceeds, after deducting Cowen's commission		
December 2021 ATM Agreement	74,304	\$	1,196	\$ 16.10	\$	1,161	
November 2021 ATM Agreement	4,051,534		52,901	13.06		51,313	
September 2020 ATM Agreement	5,226,521		49,996	9.57		48,496	
•	9,352,359	\$	104,093	\$ 11.13	\$	100,970	

In December 2021, we entered into a Sales Agreement (the "December 2021 ATM Agreement") with Cowen and Company, LLC, or Cowen, pursuant to which we can offer and sell, from time to time at our sole discretion through Cowen, as our sales agent, shares of common stock having an aggregate offering price of up to \$200.0 million. Any shares of common stock sold will be issued pursuant to our automatic shelf registration statement on Form S-3ASR (File No. 333-261774). We will pay Cowen a commission equal to 3.0% of the gross sales proceeds of any shares of common stock sold through Cowen under the December 2021 ATM Agreement and also have provided Cowen with indemnification and contribution rights. As of December 31, 2021, we have sold an aggregate of 74,304 shares of our common stock for gross proceeds of approximately \$1.2 million at a weighted average purchase price of \$16.10 per share pursuant to the December 2021 ATM Agreement. As of March 15, 2022, an additional of 424,043 shares of our common stock were sold pursuant to the December 2021 ATM Agreement for gross proceeds of approximately \$6.4 million at a weighted average purchase price of \$15.04 per share. Approximately \$192.4 million remains available under the automatic shelf registration statement.

We previously entered into a Sales Agreement with Cowen in November 2021 (the "November 2021 ATM Agreement") and a Sales Agreement with Cowen in September 2020 (the "September 2020 ATM Agreement"), pursuant to which we could offer and sell, from time to time at our sole discretion through Cowen, as our sales agent, shares of common stock having an aggregate offering price of up to \$100.0 million and \$50.0 million, respectively. Shares of common stock sold under the November 2021 ATM Agreement and September 2020 ATM Agreement (the "Prior ATM Agreements") were issued and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-248752). We paid Cowen a commission equal to 3.0% of the gross sales proceeds of shares of common stock sold under the Prior ATM Agreements. The November 2021 ATM Agreement was terminated as of December 20, 2021, and the September 2020 ATM Agreement was terminated as of November 19, 2021. Following termination, we will not sell any additional shares of common stock pursuant to the Prior ATM Agreements.

#### **Debt Facility**

In November 2021, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance LLC, or Oxford Finance, which provides up to \$50.0 million in borrowing capacity across five potential tranches. The initial tranche of \$10.0 million was funded at the closing of the Loan Agreement, and an additional \$10.0 million will be available at our election from July 1, 2022 to December 30, 2022. Subsequent tranches of up to \$20.0 million each would become available upon achieving milestones related to our MISSION Phase 2 clinical trial, our PRESIDIO Phase 2 clinical trial and our KZR-261 Phase 1 clinical trial, up to the aggregate maximum amount of \$50.0 million. The Loan Agreement bears interest at a floating per annum rate (based on the actual number of days elapsed divided by a year of 360 days) equal to the sum of (a) the greater of (i) the 30-day U.S. LIBOR rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue and (ii) 0.08%, plus (b) 7.87%. We are required to make monthly interest-only payments prior to the amortization date of January 1, 2025, subject to a potential one-year extension upon satisfaction of certain conditions. The loan facility is secured by all assets except intellectual property, which is subject to a negative pledge, and will mature on November 1, 2026. There are no warrants or financial covenants associated with the Loan Agreement.

# **Funding Requirements**

We believe that our available cash, cash equivalents and short-term investments and continued access to our term loan are sufficient to fund existing and planned cash requirements. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, clinical costs, legal and other regulatory expenses and general overhead costs. We have based our estimates on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we currently expect.

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, KZR-261 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.

Our material cash requirements also include the following contractual obligations as of December 31, 2021 (in millions). For additional information, see our consolidated financial statements.

CONTRACTUAL OBLIGATIONS	r	TOTAL	Less than 1 year	1-3 years	3-5 years	More than 5 years
Debt <sup>(1)</sup>	\$	13.8	\$ 0.8	\$ 2.0	\$ 11.0	\$ _
Operating leases <sup>(2)</sup>		5.2	1.6	3.3	 0.3	_
Total obligations	\$	13.8	\$ 0.8	\$ 2.0	\$ 11.0	\$ _

- (1) Debt obligations include principal, future interest payments and the final payment fee due on maturity. Interest payments include interests on variable rate debt based on the outstanding balances and the applicable initial rates at the closing of the Loan Agreement with Oxford Finance. Refer to Note 7 of our audited financial statements for payments due under the term loans.
- (2) 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 above 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 Onyx License Agreement. 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.

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. Funding may not be available to us on acceptable terms, or at all. The COVID-19 pandemic and the Russian incursion into the Ukraine have already resulted in significant disruption of global financial markets. If such a disruption occurs, we could experience an inability to access additional capital, which could in the future negatively affect our operations. 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

Discussion of our cash flow activities for the year ended December 31, 2019 is included in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 11, 2021.

The following summarizes our cash flows for the periods indicated:

	Year Ended December 31,				
		2021	2020		
(dollars in millions)					
Net cash used in operating activities	\$	(42.4) \$	(36.9)		
Net cash used in investing activities		(28.4)	(56.5)		
Net cash provided by financing activities		112.6	99.6		
Effect of exchange rate changes on cash and cash equivalents		(0.1)	0.1		
Net increase in cash and cash equivalents	\$	41.7 \$	6.3		

# Cash Flows from Operating Activities

During the year ended December 31, 2021, cash used in operating activities was \$42.4 million, which consisted of a net loss of \$54.6 million and a net change of \$1.2 million in our net operating assets and liabilities, and adjusted by non-cash charges of \$11.0 million. The non-cash charges consisted of \$1.5 million for depreciation and amortization, \$7.6 million for stock-based compensation expense, \$1.8 million of amortization of premium and discounts on marketable securities, and \$0.1 million of non-cash interest expense. The change in our net operating assets and liabilities was primarily due to a decrease of \$1.1 million in prepaid expenses and other current assets and an increase of \$1.2 million in accounts payable and accrued expenses due to timing of payments and increased clinical and manufacturing expenditures, offset by a decrease of \$1.0 million in operating lease liabilities.

During the year ended December 31, 2020, cash used in operating activities was \$36.9 million, which consisted of a net loss of \$41.7 million and a net change of \$2.0 million in our net operating assets and liabilities, and adjusted by non-cash charges of \$6.8 million. The non-cash charges consisted of \$1.5 million for depreciation and amortization and \$4.9 million for stock-based compensation expense, \$0.3 million of amortization of premium and discounts on marketable securities. The change in our net operating assets and liabilities was primarily due to an increase of \$1.4 million in prepaid expenses and other current assets and a decrease of \$0.9 million in operating lease liabilities, offset by an increase of \$0.3 million in accounts payable and accrued expenses due to timing of payments and increased clinical and manufacturing expenditures.

# Cash Flows from Investing Activities

During the year ended December 31, 2021, net cash used in investing activities was \$28.4 million primarily relating to the purchases of marketable securities exceeding maturities of such marketable securities. Payments for the purchases of property and equipment was \$0.3 million during the year ended December 31, 2021.

During the year ended December 31, 2020, net cash used in investing activities was \$56.5 million primarily relating to the purchases of marketable securities exceeding maturities of such marketable securities. Payments for the purchases of property and equipment was \$0.2 million during the year ended December 31, 2020.

# Cash Flows from Financing Activities

During the year ended December 31, 2021, cash provided by financing activities was \$112.6 million, consisting of \$101.0 million of net proceeds received from the at-the-market offering programs described above, \$9.5 million of net proceeds received under the Loan Agreement with Oxford Finance, and \$2.1 million from the issuance of common stock pursuant to our employee equity plans.

During the year ended December 31, 2020, cash provided by financing activities was \$99.6 million, consisting of \$99.2 million of net proceeds received from the underwritten public offering and \$0.4 million from the issuance of common stock pursuant to our employee equity plans.

# **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 \$208.4 million as of December 31, 2021, which consisted of bank deposits, highly liquid U.S. Treasury money market funds, U.S. Treasury securities, U.S. agency bonds, commercial paper 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, 2021, our cash equivalents and marketable securities had an average maturity of approximately five months and the longest maturity was eleven months. 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 \$0.7 million of our cash balance was located in Australia as of December 31, 2021. 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.

# 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, 2021. Based on the evaluation of our disclosure controls and procedures as of December 31, 2021, 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.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2021 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control – Integrated Framework" (2013). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2021.

# 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.

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.

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

Not applicable.

# **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 "Proposal 1: Election of Directors," "Information About Our Executive Officers," "Information Regarding the Board and Corporate Governance" and "Delinquent Section 16(a) Reports," if applicable, in our 2022 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 Officer and Director Compensation" in our 2022 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 "Equity Compensation Plan Information" and "Security Ownership of Certain Beneficial Owners and Management" in our 2022 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 "Transactions With Related Persons" and "Information Regarding the Board and Corporate Governance – Board Independence" in our 2022 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" in our 2022 Proxy Statement.

# PART IV

# Item 15. Exhibit 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

Report of Independent Registered Public Accounting Firm (PCAOB ID: 185)	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
Consolidated Statements of Comprehensive Loss	F-5
Consolidated Statements of Stockholders' Equity	F-6
Consolidated Statements of Cash Flows	F-7
Notes to Consolidated Financial Statements	F-8

# (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

Exhibit	
Number	
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's
	<u>Current Report on Form 8-K (File No. 001-38542), filed with the Commission on June 26, 2018).</u>
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).
4.3	Description of the Company's Securities (incorporated by incorporated by reference to Exhibit 4.3 to the Company's Annual Report on
	Form 10-K (File No. 001-38542), filed with the Commission on March 12, 2020).
4.4	Form of Pre-Funded Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-
	38542), filed with the SEC on February 3, 2020).
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.
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).

Table of Conten	
10.9+	Non-Employee Director Compensation Policy.
10.10+	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).
10.11+	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).
10.12+	Amended and Restated Executive Employment Agreement between the Company and Marc L. Belsky, dated January 14, 2020
	(incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K (File No. 001-38542), filed with the
	Commission on March 12, 2020.
10.13+	Executive Employment Agreement between the Company and Noreen Henig, M.D., dated April 25, 2020 (incorporated by reference to
	Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (File No. 001-38542), filed with the Commission on May 7, 2020.
10.14†	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
	<u>June 8, 2018).</u>
10.15	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).
10.16	Confirmation of Lease Terms between the Company and AP3-SF1 4000 Shoreline, LLC, effective as of March 1, 2018 (incorporated herein
	by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K (File No. 001-38542), filed with the Commission on March
10.45	<u>26, 2019).</u>
10.17	Loan and Security Agreement, dated as of November 4, 2021, by and between the Company and Oxford Finance LLC.
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
22.4	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
24.2	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
32.1*	Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 <sup></sup>	<u>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.</u>
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded
101.1115	within the Inline XBRL Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.SCH 101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.CAL 101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.DEF 101.LAB	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAD	Initie ABRL Taxonomy Extension Laber Lilikouse Document

<sup>\*</sup> 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.

Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibit 101).

Inline XBRL Taxonomy Extension Presentation Linkbase Document

# Item 16. Form 10-K Summary

None.

101.PRE

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<sup>+</sup> Indicates a management contract or compensatory plan.

<sup>†</sup> 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 17, 2022 By: /s/ John Fowler

John Fowler

Chief Executive Officer (Principal Executive Officer)

March 17, 2022

By: /s/ Marc Belsky Marc 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 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 17, 2022
/s/ Marc Belsky Marc Belsky	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 17, 2022
/s/ Jean-Pierre Sommadossi, Ph.D. Jean-Pierre Sommadossi, Ph.D.	Chairman of the Board of Directors	March 17, 2022
/s/ Franklin Berger Franklin Berger	Director	March 17, 2022
/s/ Graham Cooper Graham Cooper	Director	March 17, 2022
/s/ Elizabeth Garner, M.D. Elizabeth Garner, M.D.	Director	March 17, 2022
/s/ Michael Kauffman, M.D., Ph.D. Michael Kauffman, M.D., Ph.D.	Director	March 17, 2022
/s/ Christopher Kirk, Ph.D. Christopher Kirk, Ph.D.	President, Chief Scientific Officer and Director	March 17, 2022
/s/ Micki Klearman, M.D. Micki Klearman, M.D.	Director	March 17, 2022
/s/ Courtney Wallace Courtney Wallace	Director	March 17, 2022

# INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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#### 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, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2021, 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 17, 2022

# **KEZAR LIFE SCIENCES, INC. Consolidated Balance Sheets**

(In thousands, except share and per share data)

	Dece	ember 31, 2021	December 31, 2020
Assets			
Current assets:			
Cash and cash equivalents	\$	62,882	\$ 21,228
Marketable securities		145,473	119,219
Prepaid expenses		2,570	2,733
Other current assets		729	 1,631
Total current assets		211,654	144,811
Property and equipment, net		3,283	3,435
Operating lease right-of-use asset		2,714	3,314
Other assets		282	 282
Total assets	\$	217,933	\$ 151,842
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable	\$	2,028	\$ 2,358
Accrued liabilities		4,985	3,021
Operating lease liabilities, current		1,199	1,042
Other liabilities, current		_	21
Total current liabilities		8,212	 6,442
Operating lease liabilities, noncurrent		3,223	4,422
Debt, noncurrent		9,622	 <u> </u>
Total liabilities		21,057	10,864
Stockholders' equity:			
Common stock, \$0.001 par value, 125,000,000 shares authorized as of December 31, 2021 and 2020; 56,259,747 and 46,359,743 shares issued and outstanding as of December 31, 2021 and 2020, respectively		56	46
Preferred stock, \$0.001 par value, 10,000,000 shares authorized, zero shares issued and outstanding as of December 31, 2021 and 2020		_	_
Additional paid-in capital		377,765	267,093
Accumulated other comprehensive loss		(291)	(137)
Accumulated deficit		(180,654)	 (126,024)
Total stockholders' equity		196,876	140,978
Total liabilities and stockholders' equity	\$	217,933	\$ 151,842

# KEZAR LIFE SCIENCES, INC. Consolidated Statements of Operations

(In thousands except share and per share data)

**Year Ended** December 31, 2021 2019 2020 Operating expenses: Research and development \$ 38,935 \$ 30,981 \$ 27,363 General and administrative 15,724 11,969 9,979 Total operating expenses 54,659 42,950 37,342 Loss from operations (54,659)(42,950)(37,342)Interest income 188 1,208 2,255 Interest expense (159)Net loss (54,630) (41,742) (35,087)\$ \$ \$ Net loss per common share, basic and diluted (1.04)(0.95)(1.84)Weighted-average shares used to compute net loss per common share, basic and diluted 52,759,335 44,004,190 19,083,826

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

	Year Ended								
	December 31,								
		2021		2020		2019			
Net loss	\$	(54,630)	\$	(41,742)	\$	(35,087)			
Other comprehensive (loss) income, net of tax:									
Foreign currency translation adjustments		(50)		82		(45)			
Unrealized (loss) gain on marketable securities		(104)		(23)		52			
Total other comprehensive (loss) income, net of tax		(154)		59		7			
Comprehensive loss	\$	(54,784)	\$	(41,683)	\$	(35,080)			

# KEZAR LIFE SCIENCES, INC. Consolidated Statements of Stockholders' Equity

(In thousands, except share and per share amounts)

		N STOCK	ADDITIONAL PAID-IN	ACCUMULATED OTHER COMPREHENSIVE	ACCUMULATED	TOTAL STOCKHOLDERS'
	SHARES	AMOUNTS	CAPITAL	INCOME (LOSS)	DEFICIT	EQUITY
Balance at December 31, 2018	19,114,421	\$ 19	\$ 158,176	\$ (203)	\$ (49,195)	\$ 108,797
Issuance of common stock under employee stock incentive plans	93,656	_	272	_	_	272
Vesting related to shares of common stock issued pursuant to early exercises	_	_	50	_	_	50
Stock-based compensation expense	_	_	4,007	_	_	4,007
Other comprehensive income	_	_	_	7	_	7
Net loss	_	_	_	_	(35,087)	(35,087)
Balance at December 31, 2019	19,208,077	19	162,505	(196)	(84,282)	78,046
Issuance of common stock and pre-funded warrants through underwritten offerings, net of offering costs of \$6,748	26,984,001	27	99,134	_	_	99,161
Issuance of common stock under employee stock incentive plans	167,665	_	470	_	_	470
Vesting related to shares of common stock issued pursuant to early exercises	_	_	41	_	_	41
Stock-based compensation expense	_	_	4,943	_	_	4,943
Other comprehensive income	_	_	_	59	_	59
Net loss					(41,742)	(41,742)
Balance at December 31, 2020	46,359,743	46	267,093	(137)	(126,024)	140,978
Issuance of common stock under the ATM Agreements, net of offering costs of \$3,123	9,352,359	9	100,986	_	_	100,995
Issuance of common stock under employee stock incentive plans	547,645	1	2,069	_	_	2,070
Vesting related to shares of common stock issued pursuant to early exercises	_	_	21	_	_	21
Stock-based compensation expense	_	_	7,596	_	_	7,596
Other comprehensive income	_	_	_	(154)	_	(154)
Net loss					(54,630)	(54,630)
Balance at December 31, 2021	56,259,747	\$ 56	\$ 377,765	<u>\$ (291)</u>	\$ (180,654)	\$ 196,876

# KEZAR LIFE SCIENCES, INC. Consolidated Statements of Cash Flows

(In thousands)

				Year Ended December 31,		
		2021	2020			2019
Cash flows from operating activities:						
Net loss	\$	(54,630)	\$	(41,742)	\$	(35,087)
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization		1,510		1,544		1,301
Stock-based compensation		7,596		4,943		4,007
Amortization of premiums and discounts on marketable securities		1,770		317		(979)
Amortization of debt discount and issuance costs and other non-cash interest		91		_		_
Changes in operating assets and liabilities						
Prepaid expenses and other current assets		1,051		(1,424)		(553)
Accounts payable and accrued liabilities		1,217		313		2,208
Operating lease liabilities and other liabilities		(1,042)		(900)		(774)
Net cash used in operating activities		(42,437)		(36,949)		(29,877)
Cash flows from investing activities:						
Purchases of property and equipment		(316)		(194)		(607)
Purchases of marketable securities		(156,378)		(225,728)		(102,255)
Maturities of marketable securities		128,250		169,424		123,281
Net cash (used in) provided by investing activities		(28,444)		(56,498)		20,419
Cash flows from financing activities:						
Proceeds from long-term debt, net of debt discount and issuance costs of \$469		9,531		_		_
Proceeds from issuance of common stock under at-the-market offerings, net of issuance costs		100,970		_		_
Proceeds from sale of common stock and pre-funded warrants in public offerings, net of offering costs		_		99,186		_
Proceeds from issuance of common stock under employee						
stock incentive plans		2,084		456		272
Net cash provided by financing activities		112,585		99,642		272
Effect of exchange rate changes on cash and cash equivalents		(50)		82		(45)
Net increase (decrease) in cash and cash equivalents		41,654		6,277		(9,231)
Cash and cash equivalents at the beginning of period		21,228		14,951		24,182
Cash and cash equivalents at the end of period	\$	62,882	\$	21,228	\$	14,951
Supplemental disclosures of noncash investing and financing information:						
Reclassification of employee stock liability to equity upon vesting	\$	21	\$	41	\$	50
Purchase of property and equipment in accounts payable	\$	442	\$	_	\$	
Unpaid offering costs in accrued liabilities	\$	_	\$	25	\$	_
Supplemental disclosures	*		_		Ť	
Cash paid for interest	\$	69	\$		\$	
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# KEZAR LIFE SCIENCES, INC. Notes to 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 immune-mediated diseases and cancer. The Company's principal operations are in South San Francisco, California, and it operates in one segment.

# 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 candidates, KZR-616 and KZR-261. 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 \$180.7 million as of December 31, 2021. 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 cash, cash equivalents and marketable securities as of December 31, 2021 will be sufficient to fund the Company's cash requirements for at least 12 months following the issuance of these financial statements.

During 2021, the Company sold an aggregate of 9,352,359 shares of its common stock at a weighted average purchase price of \$11.13 per share pursuant to the Company's at-the-market offering programs for net proceeds of approximately \$101.0 million after deducting \$3.1 million commission paid. Between January 1, 2022 and March 15, 2022, the Company sold an additional 424,043 shares of common stock pursuant to the ATM program for gross proceeds of approximately \$6.4 million at a weighted average purchase price of \$15.04 per share.

In November 2021, the Company entered into a loan and security agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford Finance"), which provides the Company up to \$50.0 million in borrowing capacity across five potential tranches. The initial tranche of \$10.0 million was funded at the closing of the Loan Agreement.

On June 11, 2020, the Company completed an underwritten public offering of 7,590,909 shares of its common stock and, to certain investors in lieu thereof, pre-funded warrants to purchase 909,091 shares of its common stock at an exercise price of \$0.001 per share (the "June Offering"). The public offering price of the Company's common stock was \$5.50 per share and the public offering price of each pre-funded warrant was \$5.499 per underlying share. In July 2020, the underwriters exercised an option to purchase an additional 427,707 shares of common stock. The net proceeds from the June Offering were approximately \$45.8 million, after deducting underwriting discounts and commissions and other offering expenses paid by us. The Company's existing stockholder, Equal Talent Investments Limited, and one of the Company's directors purchased an aggregate of approximately \$8.5 million of common stock in the June Offering.

On February 4, 2020, the Company completed an underwritten public offering of 18,965,385 shares of its common stock, which includes the full exercise of the underwriters' option to purchase additional shares of common stock, and, to certain investors in lieu thereof, pre-funded warrants to purchase 2,884,615 shares of its common stock at an exercise price of \$0.001 per share (the "February Offering"). The public offering price of the Company's common stock was \$2.60 per share and the public offering price of each pre-funded warrant was \$2.599 per underlying share. The net proceeds from the February Offering were approximately \$53.4 million, after deducting underwriting discounts and commissions and other offering expenses paid by us. The Company's existing stockholder, Morningside Ventures Investments Ltd, and certain of the Company's officers and directors purchased an aggregate of approximately \$10.4 million of common stock in the February Offering.

#### 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 ("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 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 valuation of marketable securities, 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.

The Company also anticipates that the COVID-19 pandemic will continue to have an impact on the clinical and preclinical development timelines for its clinical and preclinical programs. Estimates and assumptions about future events and their effects cannot be determined with certainty and therefore require the exercise of judgment. As of the date of issuance of these financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update its estimates, assumptions and judgments or revise the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information is obtained and are recognized in the consolidated financial statements as soon as they become known. Actual results could differ from those estimates and any such differences may be material to the Company's consolidated financial statements.

## Significant Risks and Uncertainties

The Company has implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on its business. The extent to which the COVID-19 pandemic impacts the Company's business, preclinical and clinical development and regulatory efforts, corporate development objectives and the value of and market for its common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing, safety measures and business closure requirements in the United States, Europe and other countries, and the effectiveness of actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic could have a material adverse effect on the Company's business, financial condition, results of operations and growth prospects.

In addition, the Company is subject to other challenges and risks specific to its business and its ability to execute on its strategy, as well as risks and uncertainties common to companies in the biotechnology industry with development operations, including, without limitation, risks and uncertainties associated with: obtaining regulatory feedback regarding the Company's product candidates; delays or problems in the supply of its product candidates; loss of single source suppliers or their failure to comply with manufacturing regulations; identifying, acquiring or in-licensing additional technologies or product candidates; clinical development and the inherent uncertainty of clinical success; the challenges of protecting and enhancing its intellectual property rights; and complying with applicable regulatory requirements. In addition, to the extent the ongoing COVID-19 pandemic adversely affects the Company's business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties discussed above.

# **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

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. The Company has no restricted cash.

#### Marketable Securities

All marketable securities have been classified as "available-for-sale" and are carried at estimated fair value, based upon quoted market prices or pricing models for similar securities. The Company considers its available-for-sale portfolio as available for use in current operations. Unrealized gains and losses are excluded from earnings and are included in other comprehensive income or loss and reported as a separate component of stockholders' equity or deficit until realized or until a determination is made that an other-than-temporary decline in market value has occurred. Realized gains and losses as well as credit losses, 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. If a credit loss does exist for available-for-sale debt securities and should be recognized, an allowance will be recorded rather than a write-down of the amortized cost basis. To date, no such credit losses have occurred or have been recorded.

#### 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. As of December 31, 2021, the majority of the Company's cash, cash equivalents and marketable securities were held by financial institutions in the United States, while approximately \$0.7 million was held by a financial institution in Australia. Such deposits in the United States were in excess of insured limits.

# Impairment of Long-Lived Assets

Long-lived assets include property and equipment. The Company reviews the carrying value of its long-lived assets for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset 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, 2021, 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.

#### Lagrage

At lease commencement, the Company records a lease liability based on the present value of lease payments over the expected lease term. The Company calculates the present value of lease payments using the discount rate implicit in the lease, unless that rate cannot be readily determined. In that case, the Company uses its incremental borrowing rate, which is the rate of interest that the Company would have to pay to borrow on a collateralized basis an amount equal to the lease payments over the expected lease term. The Company records a corresponding right-of-use ("ROU") lease asset based on the lease liability, adjusted for any lease incentives received and any initial direct costs paid to the lessor prior to the lease commencement date.

After lease commencement, the Company measures its leases as follows: (i) the lease liability based on the present value of the remaining lease payments using the discount rate determined at lease commencement; and (ii) the ROU lease asset based on the remeasured lease liability, adjusted for any unamortized lease incentives received, any unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease agreement. Any lease incentives received and any initial direct costs are amortized on a straight-line basis over the expected lease term. Rent expense is recorded on a straight-line basis over the expected lease term.

The Company does not recognize ROU assets or lease liabilities for short-term leases with terms less than 12 months and separately accounts for lease and non-lease components for all of its leases.

#### **Debt Issuance Costs and Debt Discounts**

Debt issuance costs include legal fees, accounting fees, and other direct costs incurred in connection with the execution of the Company's debt financing. Debt discounts represent costs paid to the lenders. Debt issuance costs and debt discounts are deducted from the carrying amount of the debt liability and are amortized to interest expense over the term of the related debt using the effective interest method.

# **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 consultants 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 \$0, \$58,000 and \$635,000 as a reduction of research and development expenses for the years ended December 31, 2021, 2020 and 2019, respectively, in connection with the research and development tax incentive from the ATO. As of December 31, 2021 and 2020, the research and development tax credit receivable was \$70,000 and \$766,000, respectively, which is included in other current assets in the consolidated balance sheets.

#### Stock-Based Compensation

Stock-based awards issued to employees, directors and nonemployee consultants, 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 expected vesting period. For share-based awards that vest subject to a performance condition, the Company will recognize compensation cost for awards if and when the Company concludes that it is probable that the awards with a performance condition will be achieved on an accelerated attribution method. The Company accounts for forfeitures as they occur by reversing any expense recognized for unvested awards.

#### **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 and pre-funded warrants 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. The pre-funded warrants are included in the computation of basic and diluted net loss per common share as the exercise price is negligible and the pre-funded warrants are fully vested and exercisable. Common share equivalents are only included in the calculation of diluted net loss per common share when their effect is dilutive.

## **Recently Issued Accounting Pronouncements**

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance.* ASU 2021-10 requires entities to disclose certain information about the nature of certain governmental assistance received, including the nature of the transaction and the related accounting policy, the financial statement line items impacted by the assistance, as well as the significant terms and conditions of the transactions. The standard is effective for annual reporting periods beginning after December 15, 2021, with early adoption permitted. The adoption on ASU 2021-10 is not expected to have a material impact on the Company's consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04 Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 370-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40); Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force), which clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The standard is effective for all entities for fiscal years beginning after December 15, 2021. Adoption of this standard will not have a material impact on the Company's consolidated financial statements.

In March 2020, the FASB issued ASU 2020-04, *Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. ASU 2020-04 is intended to provide optional expedients and exceptions to the U.S. GAAP guidance on contract modifications and hedge accounting to ease the financial reporting burdens related to the discontinuation of the London Interbank Offered Rate ("LIBOR") or by another reference rate expected to be discontinued. The FASB also issued ASU 2021-01, *Reference Rate Reform (Topic 848): Scope*, in January 2021. It clarifies that certain optional expedients and exceptions apply to derivatives that are affected by the discounting transition. The amendments in this ASU affect the guidance in ASU No. 2020-04 and are effective in the same timeframe as ASU 2020-04. The relief offered by this guidance, if adopted, is available to companies for the period March 12, 2020 through December 31, 2022. The Company's Loan Agreement with Oxford Finance includes a provision for the determination of a benchmark replacement rate as a successor to the LIBOR rate, therefore the Company does not expect the discontinuation of LIBOR to have an impact on its consolidated financial statements.

#### 3. Fair Value Measurements

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, 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.

**Financial Assets:** 

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.

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 did not have any assets or liabilities measured using Level 3 inputs as of December 31, 2021 or 2020.

The following table summarizes the Company's financial assets measured at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above (in thousands):

December 31, 2021

Level 3

U.S. Treas	ury money market funds	\$	60,375	\$ 60,375	\$	_	\$ 
U.S. Treas	ury securities		82,106	82,106		_	_
Commerci	al paper		46,687	_		46,687	_
Corporate	debt securities		15,481	_		15,481	_
U.S. Gove	rnment agency bonds		1,199	_		1,199	_
Total		\$	205,848	\$ 142,481	\$	63,367	\$ 
		-					 
				December	31, 20	)20	
Financial As	ssets:		Total	 December Level 1	31, 20	)20 Level 2	 Level 3
	ssets: ury money market funds	\$	<b>Total</b> 19,347	\$	31, 20		\$ Level 3
U.S. Treas		\$		\$ Level 1		Level 2	\$ Level 3
U.S. Treas	ury money market funds ury securities	\$	19,347	\$ Level 1 19,347		Level 2	\$ Level 3
U.S. Treas U.S. Treas Commerci	ury money market funds ury securities	\$	19,347 107,708	\$ Level 1 19,347		Level 2	\$ Level 3 — — — — — — — — — — — — — — — — — —
U.S. Treas U.S. Treas Commerci	ury money market funds ury securities al paper	\$	19,347 107,708 1,000	\$ Level 1 19,347		Level 2 — — — — 1,000	\$ Level 3 — — — — — — — — — — — — — — — — — —

#### 4. Available-for-Sale Securities

The following table is a summary of available-for-sale securities recorded in cash and cash equivalents or marketable securities in the Company's consolidated balance sheets as of December 31, 2021 and 2020 (in thousands):

	December 31, 2021							
Financial Assets:		Amortized Cost		Unrealized Gains	1	Unrealized Losses		Fair Value
U.S. Treasury money market funds	\$	60,375	\$	_	\$	_	\$	60,375
U.S. Treasury securities		82,204		_		(98)		82,106
Commercial paper		46,678		13		(4)		46,687
Corporate debt securities		15,486		_		(5)		15,481
U.S. agency bonds		1,200		_		(1)		1,199
Total	\$	205,943	\$	13	\$	(108)	\$	205,848

	December 31, 2020								
Financial Assets:	Amo	rtized Cost		Unrealized Gains		Unrealized Losses		Fair Value	
U.S. Treasury money market funds	\$	19,347	\$	_	\$	_	\$	19,347	
U.S. Treasury securities		107,703		10		(5)		107,708	
Commercial paper		998		2		_		1,000	
Corporate debt securities		10,509		3		(1)		10,511	
Total	\$	138,557	\$	15	\$	(6)	\$	138,566	

The Company has not recognized an allowance for credit losses on any securities in an unrealized loss position as of December 31, 2021 and 2020.

The following table displays additional information regarding gross unrealized losses and fair value by major security type for available-for-sale securities in an unrealized loss position as of December 31, 2021 and 2020 (in thousands):

	December 31, 2021				December 31, 2020			
	Less than 12 consecutive months					Less than 12 con	secutive	months
	F	air Value	Unrea	lized Losses		Fair Value	Unrea	lized Losses
U.S. Treasury securities	\$	82,106	\$	(98)	\$	43,202	\$	(5)
Commercial paper		13,734		(4)		_		_
Corporate debt securities		15,481		(5)		9,006		(1)
U.S. agency bonds		1,199		(1)		<u> </u>		_
Total	\$	112,520	\$	(108)	\$	52,208	\$	(6)

The Company believes that the individual unrealized losses represent temporary declines primarily resulting from interest rate changes, and intends to hold these marketable securities to their maturities.

As of December 31, 2021, the amortized cost and estimated fair value of the Company's available-for-sale securities by contractual maturity are shown below (in thousands):

	F	Amortized Cost	Estimated Fair Value
Available-for-sale securities maturing:			
In one year or less	\$	205,943	\$ 205,848
Total available-for-sale securities	\$	205,943	\$ 205,848

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, 2021. There were no sales of available-for-sale securities in any of the periods presented.

#### 5. Balance Sheet Components

#### Property and Equipment, Net

Property and equipment, net consisted of the following as of December 31, 2021 and 2020 (in thousands):

	Dec			ecember 31, 2020
Leasehold improvements	\$	3,268	\$	3,268
Furniture, laboratory and office equipment		3,423		2,750
Computer equipment		244		159
Total property and equipment		6,935		6,177
Less accumulated depreciation and amortization		(3,652)		(2,742)
Property and equipment, net	\$	3,283	\$	3,435

Depreciation expense was \$0.9 million, \$0.9 million, and \$0.9 million for the year ended December 31, 2021, 2020, and 2019, respectively.

#### **Accrued Liabilities**

Accrued liabilities consisted of the following as of December 31, 2021 and 2020 (in thousands):

	Dec	ember 31, 2021	December 31, 2020		
Accrued preclinical and research costs	\$	1,043	\$	461	
Accrued clinical costs		1,642		929	
Accrued employee-related costs		1,970		1,355	
Accrued professional services		231		103	
Other		99		173	
Total accrued liabilities	\$	4,985	\$	3,021	

#### 6. Lease

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 contractually specified minimum rent and annual rent increases for the operating lease are included in the measurement of the ROU asset and related lease liabilities. Under the lease arrangement, the Company may be required to pay directly, or reimburse the lessor for real estate taxes, insurance, utilities, maintenance and other operating costs. Such amounts are generally variable and therefore not included in the measurement of the ROU asset and related lease liability but are instead recognized as variable lease expense in the Company's Consolidated Statements of Operations when they are incurred. The operating lease agreement has one option to extend the lease term for a period of five years at the fair market rate at the time of the extension. The option to extend the lease was not recognized as part of the Company's lease liability and ROU asset as the Company determined the renewal rent costs are uncertain and the option is not reasonably certain to be exercised.

As of December 31, 2021, the weighted average remaining lease term was 3.16 years and the weighted average discount rate used to determine the operating lease liability was 10.0%.

Information related to the Company's ROU asset and related lease liabilities were as follows (in thousands):

	For the Year Ended December 31,					
		2021		2020		2019
Cash paid for operating lease liabilities	\$	1,042	\$	900	\$	774
Operating lease costs		1,099		1,099		1,099
Variable lease costs		765		542		505
Maturities of lease liabilities as of December 31, 2021 were as follows for the years ending December 31:						
2022				\$		1,588
2023						1,635
2024						1,684
2025						282
Total undiscounted lease payments						5,189
Less: imputed interest						(767)
Total lease liabilities				\$		4,422
Operating lease liabilities, current						1,199
Operating lease liabilities, noncurrent						3,223

For the years ended December 31, 2021, 2020 and 2019, the Company recognized \$1.1 million, \$1.1 million and \$1.1 million of rent expense, respectively. Variable lease costs were \$0.8 million, \$0.5 million and \$0.5 million for the years ended December 31, 2021, 2020 and 2019, respectively.

4,422

#### 7. Debt

Total operating lease liabilities

In November 2021, the Company entered into a Loan Agreement with Oxford Finance, which provides the Company up to \$50.0 million in borrowing capacity across five potential tranches. The initial tranche of \$10.0 million was funded at the closing of the Loan Agreement, and an additional \$10.0 million will be available at the Company's election from July 1, 2022 to December 30, 2022. Subsequent tranches of \$20.0 million each would become available upon achieving milestones related to the Company's MISSION Phase 2 clinical trial, PRESIDIO Phase 2 clinical trial and KZR-261 Phase 1 clinical trial, up to the aggregate maximum amount of \$50.0 million. The loan facility is secured by all assets except intellectual property, which has a negative pledge, and will mature on November 1, 2026. There are no warrants or financial covenants associated with the Loan Agreement.

The term loans bear interest at a floating per annum rate (based on the actual number of days elapsed divided by a year of 360 days) equal to the sum of (a) the greater of (i) 30-day U.S. LIBOR rate reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue and (ii) 0.08%, plus (b) 7.87%. The Company is required to make monthly interest-only payments prior to the amortization date of January 1, 2025, subject to a potential one-year extension upon satisfaction of certain conditions.

All unpaid principal and accrued and unpaid interest with respect to each term loan is due and payable in full on November 1, 2026 (the "Maturity Date"). The Company has the option to prepay the outstanding balance prior to maturity, subject to a prepayment fee of 1.0% to 2.0% depending upon when the prepayment occurs. Upon repayment of the Term Loans, the Company is required to make a final payment fee to the Lenders equal to 6.5% of the original principal amount of the Term Loans funded which will be accrued by charges to interest expense over the term of the loans using the effective interest method

The Agreement also includes subjective acceleration clauses which permit the lenders to accelerate the Maturity Date under certain circumstances, including, but not limited to, material adverse effects on a Company's financial status or otherwise. As of December 31, 2021, the Company is in compliance with all covenants in Agreement.

Interest expense was \$0.2 million for the year ended December 31, 2021. The effective interest rate on the term loans, including the amortization of the debt discount and issuance costs, and accretion of the final payment, was 11%. The components of the long-term debt balance are as follows:

	D	December 31, 2020	
Principal loan balance	\$	10,000	\$ _
Unamortized debt discount and issuance costs		(431)	_
Cumulative accretion of final fee		53	_
Long-term debt, net	\$	9,622	\$ 

As of December 31, 2021, the estimated future principal payments due were as follows:

Years Ending December 31,	
2022	\$ _
2023	_
2024	_
2025	5,217
2026	 4,783
Total	\$ 10,000

#### 8. Pre-Funded Warrants

In February 2020, the Company completed the February Offering, which included the issuance and sale of pre-funded warrants to purchase 2,884,615 shares of its common stock. The public offering price of the pre-funded warrants was \$2.599 per underlying share.

In June 2020, the Company completed the June Offering, which included the issuance and sale of pre-funded warrants to purchase 909,091 shares of its common stock. The public offering price of the pre-funded warrants was \$5.499 per underlying share.

Each pre-funded warrant entitles the holder to purchase shares of common stock at an exercise price of \$0.001 per share and expires 20 years from the date of issuance. These warrants were recorded as a component of stockholders' equity within additional paid-in capital. Per the terms of the warrant agreement, a holder of the outstanding warrant is not entitled to exercise any portion of the pre-funded warrant if, upon exercise of such portion of the warrant, the holder's ownership of the Company's common stock (together with its affiliates) or the combined voting power of the Company's securities beneficially owned by such holder (together with its affiliates) would exceed 4.99% after giving effect to the exercise ("Maximum Ownership Percentage"). Upon at least 61 days' prior notice to the Company by the warrant holder, any warrant holder may increase or decrease the Maximum Ownership Percentage to any other percentage not to exceed 19.99%. As of December 31, 2021, no shares underlying the pre-funded warrants have been exercised.

The following table represents a summary of the pre-funded warrants outstanding as of December 31, 2021.

Issue Date	Classification	Ex	ercise price	<b>Expiration Date</b>	number of snares underlying
February 4, 2020	Equity	\$	0.001	February 4, 2040	2,884,615
June 11, 2020	Equity	\$	0.001	June 11, 2040	909,091
Total Outstanding					3,793,706

#### 9. 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 could 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. As of December 31, 2021, options to purchase 5,327,356 shares of common stock were outstanding under the 2018 Plan and 709,804 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 authorized for issuance pursuant to stock awards under the 2018 Plan was 4,000,000 shares, which is the sum of (i) 1,600,692 shares plus (ii) the number of shares reserved and 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 automatically increases on January 1 of each year, beginning on January 1, 2019 and 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 prior to such increase. 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 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, 2021, options to purchase 1,617,828 shares of common stock were outstanding under the 2015 Plan.

# 2018 Employee Stock Purchase Plan

In June 2018, the Company's board of directors adopted 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 January 1 of each year, beginning on January 1, 2019 and continuing through and including January 1, 2028, 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, or a lesser number of shares determined by the Company's board of directors prior to such increase. As of December 31, 2021, 246,232 shares of common stock had been issued under the ESPP and 711,992 shares remained available for future issuance under the ESPP. The price per share of common stock to be paid by an ESPP participant on the applicable purchase date of an offering period shall be equal to 85% of the lesser of the fair market value of a share of common stock on (i) the applicable offering date or (ii) the applicable purchase date. The Company's board of directors authorized an initial six-month

offering period beginning on November 16, 2018 and ending on May 15, 2019. The Company's board of directors has subsequently authorized additional six-month offering periods, with the most recent offering period beginning on November 16, 2021.

#### **Stock Option Activity**

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

	Number of Options Outstanding	E	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	4,489,122	\$	6.14	7.8	\$ 7,134
Options granted	3,574,500	\$	5.81		
Options exercised	(439,081)	\$	3.59		\$ 2,107
Options cancelled/forfeited	(679,357)	\$	7.97		
Outstanding at December 31, 2021	6,945,184	\$	5.95	7.9	\$ 77,363
Vested and exercisable at December 31, 2021	3,369,559	\$	5.79	6.8	\$ 38,713

The weighted average grant date fair value of options granted during the years ended December 31, 2021 and 2020 was \$4.20 and \$2.76 per share, respectively. The aggregate intrinsic value of exercised stock options during the years ended December 31, 2021 and 2020 was \$2.1 million and \$0.2 million, 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 Options

The 2015 Plan allows for early exercisable option grants, which permit the holder to exercise a stock option for the purchase of common stock before the requisite service is provided (i.e., before the award is vested under its original terms); however, such arrangements permit the Company to subsequently repurchase at the exercise price any shares of common stock for which the applicable vesting conditions have not been satisfied. Under the 2015 Plan, the Company only made such early exercisable option grants to non-employee members of its board of directors.

As of December 31, 2021 and 2020, there were 0 and 8,859 shares, respectively, of nonvested common stock outstanding that were exercised early and remain 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 one year after the applicable vesting commencement date and 1/48 of the shares underlying the option each 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 with the corresponding par value in common stock and an offset in additional paid-in capital. As of December 31, 2021 and 2020, the Company recorded in other current liabilities \$0 and \$21,000, respectively, associated with shares issued upon the early exercise of stock options that are subject to repurchase.

# **Stock-Based Compensation Expense**

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

	Year Ended December 31,					
	2021		2020		2019	
Research and development	\$	2,955	\$	2,102	\$	1,777
General and administrative		4,641		2,841		2,230
Total stock-based compensation expense	\$	7,596	\$	4,943	\$	4,007

As of December 31, 2021, the unrecognized stock-based compensation cost was \$14.7 million with an estimated weighted average amortization period of 2.6 years.

The fair value of the employee stock options granted and the ESPP rights to purchase common stock of the Company is calculated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

		Options			ESPP Rights	
	Yea	r Ended December 31,		Year	Ended December 31,	
	2021	2020	2019	2021	2020	2019
Expected term (years)	5.5 - 6.1	5.5 - 6.0	5.8 - 5.9	0.5	0.5	0.5
Expected volatility	85.4 - 88.1%	83.8 - 91.9%	78.7 - 83.7%	64.0 - 77.2%	101.7 - 114.3%	73.7 - 109.9%
Risk-free interest rate	0.5 - 1.3%	0.4 - 1.6%	1.5 - 2.6%	0.0 - 0.1%	0.1 - 0.2%	1.6 - 2.4%
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 of the historical volatility of the Company's stock price and that 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.

# 10. Commitments & Contingencies

#### 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.

#### 11. 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., 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 for KZR-616, as well as royalty payments in the mid to high single digits on future annual net sales, if any.

## 12. 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 \$56,000 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 the first 4% of base compensation and incentive cash bonus (subject to statutory limits). During

the years ended December 31, 2021, 2020 and 2019, the Company recorded matching contributions of approximately \$423,000, \$326,000 and \$249,000, respectively.

#### 13. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2021, 2020 and 2019. 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 following table presents domestic and foreign components of net loss for the periods presented (in thousands):

	Year Ended December 31,					
	 2021 2020			2019		
Domestic	\$ (54,581)	\$	(41,599)	\$	(34,181)	
Foreign	(49)		(143)		(906)	
Total	\$ (54,630)	\$	(41,742)	\$	(35,087)	

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 years 2016 through 2020. The Company has utilized \$325,000, \$373,000 and \$284,000 of R&D tax credits as a reduction of payroll expenses to offset its payroll tax liabilities for the years ended December 31, 2021, 2020 and 2019, respectively.

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

	Year E	Year Ended December 31,					
	2021	2020	2019				
Federal statutory income tax rate	21.0 %	21.0 %	21.0 %				
State taxes, net of federal benefit	1.3	1.1	0.9				
Foreign tax rate differential	0.0	0.0	0.2				
Permanent differences	(2.2)	(2.7)	(1.7)				
Research and development credit	4.0	2.6	1.9				
Change in valuation allowance	(24.1)	(22.0)	(22.3)				
Provision for income taxes	%	<u> </u>	<u> </u>				

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

	Year Ended December 31,					
		2021		2020		2019
Deferred tax assets						
Reserves and accruals	\$	2,043	\$	1,665	\$	1,056
Net operating loss carryforwards		34,617		24,824		16,986
Research and development credit carryforwards		5,127		2,938		2,177
Lease Liabilities		929		1,148		1,336
Gross deferred tax assets		42,716		30,575		21,555
Valuation allowance		(41,771)		(29,410)		(20,196)
Net deferred tax assets		945		1,165		1,359
Deferred tax liabilities						
Property and equipment		(375)		(469)		(557)
Right-of-use asset		(570)		(696)		(802)
Net deferred tax assets	\$		\$		\$	

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, 2021, and December 31, 2020 have been fully offset by a valuation allowance. The valuation allowance increased approximately \$12.4 million, \$9.2 million and \$7.6 million during the years ended December 31, 2021, 2020, and 2019, respectively.

As of December 31, 2021, the Company had federal net operating loss ("NOL") carryforward of \$156.4 million and a federal research and development tax credit carryforward of \$4.6 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 \$134.4 million generated from years ended after December 31, 2017, carryforward indefinitely. As of December 31, 2021 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 \$2.6 million, which does not expire.

As of December 31, 2021, the Company also had accumulated Australian tax losses of \$0.6 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, 2021. 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.

The Company had \$1.6 million of unrecognized tax benefits as of December 31, 2021. No liability related to uncertain tax positions is recorded on the financial statements. All uncertain tax positions are currently recorded as a reduction to the Company's deferred tax assets, which are subject to a valuation allowance. If recognized, none of the unrecognized tax benefits would affect the effective tax rate. The Company does not anticipate that the total amounts of unrecognized tax benefits will significantly increase or decrease in the next 12 months. The Company's policy is to include interest and penalties related to unrecognized tax benefits within the provision for income taxes, as necessary. The Company did not recognize any accrued interest and penalties related to gross unrecognized tax benefits related to the year ended December 31, 2021. A reconciliation of the Company's unrecognized tax benefits for the year ended December 31, 2021 and 2020 is as follows (in thousands):

	 Year Ended December 31,			
	2021		2020	
Balance at the beginning of the year	\$ 868	\$	_	
Increase related to prior year tax positions	_		381	
Increase related to current year tax positions	 775		487	
Balance at the end of the year	\$ 1,643	\$	868	

The Company files income tax returns in the United States federal jurisdiction, state jurisdictions and Australia. The Company currently has no federal, state or other jurisdictional tax examinations in progress. All years are open for examination by federal, state and Australian authorities.

# 14. 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,				
	 2021 2020		2020	2019	
Numerator:					
Net loss	\$ (54,630)	\$	(41,742)	\$	(35,087)
Denominator:					
Weighted-average shares of common stock outstanding	 52,759,335		44,004,190		19,083,826
Net loss per share, basic and diluted	\$ (1.04)	\$	(0.95)	\$	(1.84)

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:

	Y	Year Ended December 31,		
	2021	2020	2019	
Options to purchase common stock	6,945,184	4,489,122	3,107,066	
Common stock subject to future vesting	<u></u> _	8,859	30,027	
Total	6,945,184	4,497,981	3,137,093	

#### KEZAR LIFE SCIENCES, INC.

# RESTRICTED STOCK UNIT GRANT NOTICE (2018 EQUITY INCENTIVE PLAN)

Kezar Life Sciences, Inc. (the "Company"), pursuant to its 2018 Equity Incentive Plan (the "Plan"), hereby awards to Participant a Restricted Stock Unit Award for the number of shares of the Company's Common Stock ("Restricted Stock Units") set forth below (the "Award"). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this "Restricted Stock Unit Grant Notice"), and in the Plan and the Restricted Stock Unit Award Agreement (the "Award Agreement"), both of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in this Restricted Stock Unit Grant Notice or the Award Agreement and the Plan, the terms of the Plan shall control.

Date of Grant: Vesting Commencement Date: Number of Restricted Stock Units:	<u> </u>
Vesting Schedule: [	, subject to Participant's Continuous Service through each such vesting date.]

**Issuance Schedule:** 

Participant:

Subject to any Capitalization Adjustment, one share of Common Stock (or its cash equivalent, at the discretion of the Company) will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

Participant Acknowledgements:

- By Participant's signature below or by electronic acceptance or authentication in a form authorized by the Company, Participant understands and agrees that:
  - The Award is governed by this Restricted Stock Unit Grant Notice, and the provisions of the Plan and the
    Award Agreement, all of which are made a part of this document. Unless otherwise provided in the Plan,
    this Restricted Stock Unit Grant Notice and the Award Agreement (together, the "Agreement") may not be
    modified, amended or revised except in a writing signed by Participant and a duly authorized officer of the
    Company.
  - To the fullest extent permitted under the Plan and applicable law, any Withholding Taxes (as defined in the Award Agreement) applicable to the Award will be satisfied through the sale of a number of the shares of Common Stock issuable in settlement of the Award as determined in accordance with Section 11 of the Award Agreement and the remittance of the cash proceeds to the Company. Under the Agreement, the Company or, if different, the Participant's employer is authorized and directed by the Participant to make payment from the cash proceeds of this sale directly to the appropriate tax or social security authorities in an amount equal to the taxes required to be remitted. The Participant acknowledges and agrees that, as a result of Participant's authorization, the Company will have the authority to administer the Mandatory Sell to Cover (as defined in the Award Agreement) in connection with Participant's receipt of this Award.

• The Agreement sets forth the entire understanding between Participant and the Company regarding the acquisition of Common Stock and supersedes all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) other equity awards previously granted to you, and (ii) any written employment agreement, offer letter, severance agreement, written severance plan or policy, or other written agreement between the Company and you in each case that specifies the terms that should govern this Award.

By accepting this Award, Participant acknowledges having received and read the Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan and related documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

KEZAR LIFE SCIENCES, INC.

**P**ARTICIPANT

By: _ Signature Sig	gnature		
Title: Dat	te:		
Date:			
ATTACHMENTS:	Award Agreement and 2018 Equity I	Incentive Plan	

#### ATTACHMENT I

#### KEZAR LIFE SCIENCES, INC.

# 2018 Equity Incentive Plan Restricted Stock Unit Award Agreement

Pursuant to the Restricted Stock Unit Grant Notice (the "Grant Notice") and this Restricted Stock Unit Award Agreement (the "Agreement"), Kezar Life Sciences, Inc. (the "Company") has awarded you ("Participant") a Restricted Stock Unit Award (the "Award") pursuant to the Company's 2018 Equity Incentive Plan (the "Plan") for the number of Restricted Stock Units/shares indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or the Grant Notice shall have the same meanings given to them in the Plan. The terms of your Award, in addition to those set forth in the Grant Notice, are as follows.

- **1.Grant of the Award.** This Award represents the right to be issued on a future date one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 below) as indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the "Account") the number of Restricted Stock Units/shares of Common Stock subject to the Award. This Award was granted in consideration of your services to the Company.
- **2.V**ESTING. Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice. Vesting will cease upon the termination of your Continuous Service and the Restricted Stock Units credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in or to such Award or the shares of Common Stock to be issued in respect of such portion of the Award.
- **3.N**UMBER OF SHARES. The number of Restricted Stock Units subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Any additional Restricted Stock Units, shares, cash or other property that becomes subject to the Award pursuant to this Section 3, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Restricted Stock Units and shares covered by your Award. Notwithstanding the provisions of this Section 3, no fractional shares or rights for fractional shares of Common Stock shall be created pursuant to this Section 3. Any fraction of a share will be rounded down to the nearest whole share.
- **4.S**ECURITIES LAW COMPLIANCE. You may not be issued any Common Stock under your Award unless the shares of Common Stock underlying the Restricted Stock Units are either (i) then registered under the Securities Act, or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you shall not receive such Common Stock if the Company determines that such receipt would not be in material compliance with such laws and regulations.
- **5.T**RANSFER **R**ESTRICTIONS. Prior to the time that shares of Common Stock have been delivered to you, you may not transfer, pledge, sell or otherwise dispose of this Award or the shares issuable in respect of your Award, except as expressly provided in this Section 5. For example, you may not use shares that may be issued in respect of your Restricted Stock Units as security for a loan. The restrictions on transfer set forth herein will lapse upon delivery to you of shares in respect of your vested Restricted Stock Units.

- **(a) Death.** Your Award is transferable by will and by the laws of descent and distribution. At your death, vesting of your Award will cease and your executor or administrator of your estate shall be entitled to receive, on behalf of your estate, any Common Stock or other consideration that vested but was not issued before your death.
- **(b) Domestic Relations Orders.** Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your right to receive the distribution of Common Stock or other consideration hereunder, pursuant to a domestic relations order, marital settlement agreement or other divorce or separation instrument as permitted by applicable law that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this Award with the Company General Counsel prior to finalizing the domestic relations order or marital settlement agreement to verify that you may make such transfer, and if so, to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

# 6.Date of Issuance.

- (a) The issuance of shares in respect of the Restricted Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the Tax-Related Items set forth in Section 11 of this Agreement, in the event one or more Restricted Stock Units vests, the Company shall issue to you one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 above, and subject to any different provisions in the Grant Notice). Each issuance date determined by this paragraph is referred to as an "Original Issuance Date."
- (b) Notwithstanding the foregoing, if (i) selling shares of the Common Stock in the public market on the Original Issuance Date to satisfy your tax withholding obligation in accordance with Section 11 of this Agreement is prohibited for any reason, and (ii) the Company elects not to instead satisfy its tax withholding obligations by withholding shares from your distribution, then such shares shall not be delivered on such Original Issuance Date and shall instead be delivered to you on the earliest of: (1) the first date that you are not prohibited from selling shares of the Common Stock in the open market, or (2) such earlier date that the Company elects to satisfy its tax withholding obligation by withholding shares from your distribution; provided, however, that notwithstanding the foregoing, in no event will the shares be delivered to you any later than: (A) December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or (B) if and only if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the shares of Common Stock under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).
- (c) In addition and notwithstanding the foregoing, no shares of Common Stock issuable to you under this Section 6 as a result of the vesting of one or more Restricted Stock Units will be delivered to you until any filings that may be required pursuant to the Hart-Scott-Rodino ("HSR") Act in connection with the issuance of such shares have been filed and any required waiting period under the HSR Act has expired or been terminated (any such filings and/or waiting period required pursuant to HSR, the "HSR Requirements"). If the HSR Requirements apply to the issuance of any shares of Common Stock issuable to you under this Section 6 upon vesting of one or more Restricted Stock Units, such shares of Common Stock will not be issued on the Original Issuance Date and will instead be issued on the first business day on or following the date when all such HSR Requirements are satisfied and when you are permitted to sell shares of Common Stock on an established stock exchange or stock market, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities. Notwithstanding

the foregoing, the issuance date for any shares of Common Stock delayed under this Section 6(c) shall in no event be later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), unless a later issuance date is permitted without incurring adverse tax consequences under Section 409A of the Code or other applicable law.

- **(d)** The form of delivery (*e.g.*, a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.
- **7.D**IVIDENDS. You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment; provided, however, that this sentence will not apply with respect to any shares of Common Stock that are delivered to you in connection with your Award after such shares have been delivered to you.
- **8.R**ESTRICTIVE LEGENDS. The shares of Common Stock issued in respect of your Award shall be endorsed with appropriate legends as determined by the Company.
- **9.**Execution of **D**ocuments. You hereby acknowledge and agree that the manner selected by the Company by which you indicate your consent to your Grant Notice is also deemed to be your execution of your Grant Notice and of this Agreement. You further agree that such manner of indicating consent may be relied upon as your signature for establishing your execution of any documents to be executed in the future in connection with your Award.

# 10.Award not a Service Contract.

- (a) Nothing in this Agreement (including, but not limited to, the vesting of your Award or the issuance of the shares in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ or service of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.
- (b) By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the vesting schedule provided in the Grant Notice may not be earned unless (in addition to any other conditions described in the Grant Notice and this Agreement) you continue as an employee, director or consultant at the will of the Company and affiliate, as applicable (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "reorganization"). You acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with the Company's right to terminate your Continuous Service at any time, with or without your cause or notice, or to conduct a reorganization.

#### 11. WITHHOLDING OBLIGATION.

- (a) You acknowledge that, regardless of any action taken by the Company, or if different, the Affiliate employing or engaging you (the "*Employer*"), the ultimate liability for all income tax (including U.S. federal, state, and local taxes and/or non-U.S. taxes), social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items related to your participation in the Plan and legally applicable to you (the "*Tax-Related Items*") is and remains your responsibility and may exceed the amount, if any, actually withheld by the Company or the Employer. You further acknowledge that the Company and/or the Employer (i) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Award, including, but not limited to, the grant of the Award, the vesting of the Award, the issuance of shares in settlement of vesting of the Award, the subsequent sale of any shares of Common Stock acquired pursuant to the Award and the receipt of any dividends or dividend equivalent; and (ii) do not commit to and are under no obligation to reduce or eliminate your liability for Tax-Related Items. Further, if you become subject to taxation in more than one country, you acknowledge that the Company and/or the Employer (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one country.
- (b) On or before the time you receive a distribution of the shares underlying your Restricted Stock Units, and at any other time as reasonably requested by the Company in accordance with applicable law, you agree to make adequate provision for any sums required to satisfy the withholding obligations of the Company, the Employer or any Affiliate in connection with any Tax-Related Items that arise in connection with the Award (the "Withholding Taxes"). The Company shall arrange a mandatory sale (on your behalf pursuant to your authorization under this section and without further consent) of the shares of Common Stock issued in settlement upon the vesting of your Restricted Stock Units in an amount necessary to satisfy the Withholding Taxes and shall satisfy the Withholding Taxes by withholding from the proceeds of such sale (the "Mandatory Sell to Cover"). You hereby acknowledge and agree that the Company shall have the authority to administer the Mandatory Sell to Cover arrangement in its sole discretion with a registered broker-dealer that is a member of the Financial Industry Regulatory Authority as the Company may select as the agent (the "Agent") who will sell on the open market at the then prevailing market price(s), as soon as practicable on or after each date on which your Restricted Stock Units vest and the shares underlying such Restricted Stock Units are distributed, the number (rounded up to the next whole number) of the shares of Common Stock to be delivered to you in connection with the vesting and settlement of the Restricted Stock Units sufficient to generate proceeds to cover (i) the Withholding Taxes that you are required to pay pursuant to the Plan and this Agreement as a result of the vesting and settlement of the Restricted Stock Units and (ii) all applicable fees and commissions due to, or required to be collected by, the Agent with respect thereto any remaining funds shall be remitted to you.
- (c) If, for any reason, such Mandatory Sell to Cover does not result in sufficient proceeds to satisfy the Withholding Taxes, or if such Mandatory Sell to Cover is not permitted by applicable law, the Company or an Affiliate may, in its sole discretion, satisfy all or any portion of the Withholding Taxes relating to the Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company or the Employer; (ii) causing you to tender a cash payment (which may be in the form of a check, electronic wire transfer or other method permitted by the Company); or (iii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to you in connection with your Restricted Stock Units with a fair market value (measured as of the date shares of Common Stock are issued to you) equal to the amount of such Withholding Taxes; provided, however, that shares of Common Stock shall not be withheld with a value exceeding the maximum amount of tax required to be withheld by applicable law (or such lesser amount as may be necessary to avoid classification of the Award as a liability for financial accounting purposes); and to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, if applicable, such share withholding procedure will be subject to the express prior approval of the Board or Compensation Committee of the Board.

Related Items are satisfied, the Company shall have no obligation to deliver to you any Common Stock.

(e) In the event the Company's obligation to withhold arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Tax-Related Items was greater than the amount withheld by the Company or your Employer, you agree to indemnify and hold the Company and your Employer harmless from any failure by the Company or your Employer to withhold the proper amount.

Unless the tax withholding obligations of the Company and/or any Affiliate with respect to the Tax-

- **(f)** You acknowledge and agree that, as a result of your authorization under this section and without further consent, the Company will have the authority to administer the Mandatory Sell to Cover pursuant to the terms of the Award.
- (g) The Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding amounts, or other applicable withholding rates, including maximum applicable rates in your jurisdiction(s). If the maximum rate is used, any over-withheld amount may be refunded to you in cash by the Company or Employer (with no entitlement to the equivalent in shares of Common Stock), or if not refunded, you may seek a refund from the local tax authorities. You must pay to the Company and/or the Employer any amount of Tax-Related Items that the Company and/or the Employer may be required to withhold or account for as a result of your participation in the Plan that cannot be satisfied by the means previously described.
- **12.**Tax Consequences. The Company has no duty or obligation to minimize the tax consequences to you of this Award and shall not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so. You understand that you (and not the Company) shall be responsible for your own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.
- **13.**UNSECURED **O**BLIGATION. Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.
- **14.Notices.** Any notice or request required or permitted hereunder shall be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.
- **15.H**EADINGS. The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

#### 16.MISCELLANEOUS.

- **(a)** The rights and obligations of the Company under your Award shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by, the Company's successors and assigns.
- **(b)** You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.
- (c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.
- **(d)** This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.
- **(e)** All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.
- **17.GOVERNING PLAN DOCUMENT.** Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to voluntarily terminate employment upon a resignation for "good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.
- **18.**EFFECT ON **O**THER **EMPLOYEE BENEFIT PLANS.** The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating benefits under any employee benefit plan (other than the Plan) sponsored by the Company or any Affiliate except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any or all of the employee benefit plans of the Company or any Affiliate.
- **19.S**EVERABILITY. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.
- **20.O**THER **D**OCUMENTS. You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b) (1) promulgated under the Securities Act. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.
- **21.** Amendment. This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the

foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that, except as otherwise expressly provided in the Plan, no such amendment materially adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the Award as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.

**22.**Compliance with Section **409A** of the Code, including but not limited to by reason of complying with the "short-term deferral" rule set forth in Treasury Regulation Section 1.409A-1(b) (4) and any ambiguities herein shall be interpreted accordingly. Notwithstanding the foregoing, if it is determined that the Award fails to satisfy the requirements of the short-term deferral rule and is otherwise not exempt from, and determined to be deferred compensation subject to Section 409A of the Code, this Award shall comply with Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly. If it is determined that the Award is deferred compensation subject to Section 409A and you are a "Specified Employee" (within the meaning set forth in Section 409A(a)(2)(B)(i) of the Code) as of the date of your "Separation from Service" (as defined in Section 409A), then the issuance of any shares that would otherwise be made upon the date of your Separation from Service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the Separation from Service, with the balance of the shares is necessary to avoid the imposition of adverse taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is intended to constitute a "separate payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2).

\* \* \* \* \*

This Agreement shall be deemed to be signed by the Company and the Participant upon the signing by the Participant of the Restricted Stock Unit Grant Notice to which it is attached.

# ATTACHMENT II

# 2018 EQUITY INCENTIVE PLAN

## KEZAR LIFE SCIENCES, INC.

## Non-Employee Director Compensation Policy

Each member of the Board of Directors (the "*Board*") of Kezar Life Sciences, Inc. (the "*Company*") who is not also serving as an employee of the Company or any of its subsidiaries (each such member, an "*Eligible Director*") will receive the compensation described in this Non-Employee Director Compensation Policy (this "*Policy*"). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be. This Policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

## **Annual Cash Compensation**

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments to be paid thereafter. All annual cash fees are vested upon payment.

- 1. Annual Board Service Retainer:
  - a. All Eligible Directors: \$40,000
  - b. Non-executive chairperson of the Board: \$70,000 (inclusive of Annual Board Service Retainer)
- 2. Annual Committee Member Service Retainer:
  - a. Member of the Audit Committee: \$7,500
  - b. Member of the Compensation Committee: \$5,000
  - c. Member of the Nominating and Corporate Governance Committee: \$4,000
  - d. Member of the Clinical Strategy and Execution Committee: \$10,000
- 3. <u>Annual Committee Chair Service Retainer (inclusive of Committee Member Service Retainer)</u>:
  - a. Chairperson of the Audit Committee: \$15,000
  - b. Chairperson of the Compensation Committee: \$10,000
  - c. Chairperson of the Nominating and Corporate Governance Committee: \$8,000

The Company will also reimburse each of the Eligible Directors for his or her travel expenses incurred in connection with his or her attendance at Board and committee meetings. Such reimbursements shall be paid on the same date as the annual cash fees are paid.

## **Equity Compensation**

The equity compensation set forth below will be granted under the Company's 2018 Equity Incentive Plan (the "*Plan*"), subject to the approval of the Plan by the Company's stockholders. All stock options granted under this Policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock on the date of grant, and

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a term of 10 years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

- 1. <u>Initial Grant</u>: For each Eligible Director who is first elected or appointed to the Board following the effective date of this Policy, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase a number of shares of the Company's common stock equal to 52,000 shares of the Company's common stock. The shares subject to each such stock option will vest monthly over a three-year period, subject to the Eligible Director's Continuous Service (as defined in the Plan) on each vesting date.
- 2. <u>Annual Grant</u>: On the first market trading day after each annual stockholder meeting of the Company, each Eligible Director who continues to serve as a member of the Board following such stockholders meeting will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase 26,000 shares of the Company's common stock. The shares subject to each such stock option will vest in full on the date that is 12 months after the grant date, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date.

#### LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (as the same may from time to time be amended, modified, supplemented or restated, this "Agreement") dated as of November 4, 2021 (the "Effective Date") among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 115 South Union Street, Suite 300, Alexandria, VA 22314 ("Oxford"), as collateral agent (in such capacity, "Collateral Agent"), the Lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time including Oxford in its capacity as a Lender (each a "Lender" and collectively, the "Lenders"), and KEZAR LIFE SCIENCES, INC., a Delaware corporation with offices located at 4000 Shoreline Court, Suite 300, South San Francisco, CA 94080 ("Borrower"), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

# 1.ACCOUNTING AND OTHER TERMS

1.1 Accounting terms not defined in this Agreement shall be construed in accordance with GAAP. Calculations and determinations must be made in accordance with GAAP. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to "Dollars" or "\$" are United States Dollars, unless otherwise noted.

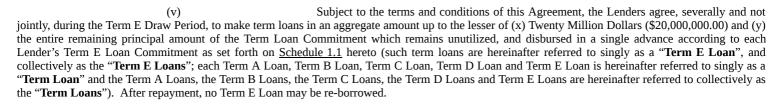
## **2.LOANS AND TERMS OF PAYMENT**

**2.1 Promise to Pay.** Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

### 2.2 Term Loans.

(a) <u>Availability</u>.

- (i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on the Effective Date in an aggregate amount of Ten Million Dollars (\$10,000,000.00) and disbursed in a single advance according to each Lender's Term A Loan Commitment as set forth on <a href="Schedule 1.1">Schedule 1.1</a> hereto (such term loans are hereinafter referred to singly as a "Term A Loan"), and collectively as the "Term A Loans"). After repayment, no Term A Loan may be re-borrowed.
- Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Term B Draw Period, to make term loans to Borrower in an aggregate up to the lesser of (x) Ten Million Dollars (\$10,000,000.00) and (y) the entire remaining principal amount of the Term Loan Commitment which remains unutilized, and disbursed in a single advance according to each Lender's Term B Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "Term B Loan", and collectively as the "Term B Loans". After repayment, no Term B Loan may be re-borrowed.
- (iii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Term C Draw Period, to make term loans in an aggregate amount up to the lesser of (x) Twenty Million Dollars (\$20,000,000.00) and (y) the entire remaining principal amount of the Term Loan Commitment which remains unutilized, and disbursed in a single advance according to each Lender's Term C Loan Commitment as set forth on <a href="Schedule 1.1">Schedule 1.1</a> hereto (such term loans are hereinafter referred to singly as a "**Term C Loan**", and collectively as the "**Term C Loans**"). After repayment, no Term C Loan may be re-borrowed.
- (iv) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Term D Draw Period, to make term loans in an aggregate amount up to the lesser of (x) Twenty Million Dollars (\$20,000,000.00) and (y) the entire remaining principal amount of the Term Loan Commitment which remains unutilized, and disbursed in a single advance according to each Lender's Term D Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "Term D Loan", and collectively as the "Term D Loans". After repayment, no Term D Loan may be re-borrowed.



- (b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to (i) twenty-three (23) months if the Amortization Date is January 1, 2025 and (ii) eleven (11) months if the Amortization Date is January 1, 2026. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).
- (c) Mandatory Prepayments. If the Term Loans are accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) the Final Payment, (iii) the Prepayment Fee, plus (iv) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Payment had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to Collateral Agent, for payment to each Lender in accordance with its respective Pro Rata Share, the Final Payment in respect of the Term Loan(s).

### (d) <u>Permitted Prepayment of Term Loans.</u>

- (i) Borrower shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least ten (10) Business Days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Payment, (C) the Prepayment Fee, plus (D) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts.
- (ii) Notwithstanding anything herein to the contrary, Borrower shall also have the option to prepay part of Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least ten (10) Business Days prior to such prepayment, (ii) prepays such part of the Term Loans in a denomination that is a whole number multiple of Five Million Dollars (\$5,000,000.00), and (iii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) the portion of outstanding principal of such Term Loans plus all accrued and unpaid interest thereon through the prepayment date, (B) the applicable Final Payment, and (C) all other Obligations that are then due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts, (D) the applicable Prepayment Fee with respect to the portion of such Term Loans being prepaid, and (E) a portion of any fee that would have otherwise been due pursuant to Section 2.2(d)(i). For the purposes of clarity, any partial prepayment shall be applied pro-rata to all outstanding amounts under each Term Loan, and shall be applied pro-rata within each Term Loan tranche to reduce amortization payments under

## 2.3 Payment of Interest on the Credit Extensions.

- (a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the Basic Rate, determined by Collateral Agent on the Funding Date of the applicable Term Loan, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full.
- (b) <u>Default Rate</u>. Immediately upon the occurrence and during the continuance of an Event of Default, the Obligations shall accrue interest at a floating per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.
- (c) 360-Day Year. Interest shall be computed on the basis of a three hundred sixty (360) day year, and the actual number of days elapsed.
- (d) Debit of Accounts. Collateral Agent and each Lender may debit (or ACH) any deposit accounts other than Excluded Accounts, maintained by Borrower or any of its Subsidiaries, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes Collateral Agent or the Lenders under the Loan Documents when due, provided that, except (i) with respect to debits (or ACH) for regularly scheduled principal and interest and (ii) as otherwise previously authorized by Borrower, Collateral Agent shall endeavor to provide prompt notice of such debit (or ACH). Any such debits (or ACH activity) shall not constitute a set-off.
- (e) Payments. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Lender's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 2:00 pm Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.
- **2.4 Secured Promissory Notes.** The Term Loans shall be evidenced by a Secured Promissory Note or Notes in the form attached as Exhibit D hereto (each a "Secured Promissory Note"), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender's Secured Promissory Note, an appropriate notation on such Lender's Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set forth on such Lender's Secured Promissory Note Record shall be prima facie evidence of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender's Secured Promissory Note Record shall not limit or otherwise affect the obligations of Borrower under any Secured Promissory Note or any other Loan Document to make payments of principal of or interest on any Secured Promissory Note when due. Upon receipt of an affidavit of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note, Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.
  - **2.5 Fees.** Borrower shall pay to Collateral Agent:

( <u>a)</u> their respective Pro Rata Shares;	<u>Final Payment</u> . The Final Payment, when due hereunder, to be shared between the Lenders in accordance with
( <u>b</u> ) their respective Pro Rata Shares;	<u>Prepayment Fee</u> . The Prepayment Fee, when due hereunder, to be shared between the Lenders in accordance with
± //	Good Faith Deposit. Borrower has paid to Collateral Agent a deposit of Fifty Thousand Dollars (\$50,000.00) (the ateral Agent's and Lenders' due diligence review and documentation process. The Good Faith Deposit will be used fective Date; provided, however, Borrower shall be responsible for the entire amount of Lenders' Expenses payable
$(\underline{d})$ and expenses for documentation and neg	<u>Lenders' Expenses</u> . All Lenders' Expenses (including reasonable and documented out-of-pocket attorneys' fees gotiation of this Agreement) incurred through and after the Effective Date, when due.

Withholding. Except as provided in the following sentence, payments received by the Lenders (or the Collateral Agent, if applicable) <u>1.1</u> from Borrower hereunder will be made free and clear of and without deduction for any and all present or future Taxes. If at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lenders, Borrower shall be permitted to make such withholding or deduction and hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority. Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.6 shall survive the termination of this Agreement. On the date of this Agreement, each Lender shall deliver, and upon a Lender Transfer, the applicable successor or assign shall deliver, to Borrower a complete and properly executed IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax or any similar or successor certificate designated by the IRS (a "Tax Certificate"). Notwithstanding anything to the contrary in this Section 2.6, so long as no Event of Default has occurred, from and after the failure of any Lender to so deliver such a Tax Certificate, the amount due from Borrower with respect to such payment or other sum payable hereunder shall not be required to be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority, until such time as the Tax Certificate has been delivered.

### **3.CONDITIONS OF LOANS**

- 3.1 Conditions Precedent to Initial Credit Extension. Each Lender's obligation to make a Term A Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:
  - (a) original Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable;
- (b) duly executed original Control Agreements with respect to any Collateral Accounts, other than Excluded Accounts, maintained by Borrower or any of its Subsidiaries;

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(d)	the certificate(s) for the Shares, together with Assignment(s) Separate from Certificate, duly executed in blank;	
 (e) the Operating Documents and good standing certificates of Borrower certified by the Secretary of State ent agency) of Borrower's jurisdiction of organization or formation and each jurisdiction in which Borrower is qualified to conduct business, edate no earlier than thirty (30) days prior to the Effective Date;		
(f)	a completed Perfection Certificate for Borrower and each of its Subsidiaries;	
(g)	the Annual Projections, for the current calendar year;	
(h)	duly executed original officer's certificate for Borrower and each Subsidiary that is a party to the Loan	

Commitment Percentage:

Documents, in a form acceptable to Collateral Agent and the Lenders;

duly executed original Secured Promissory Notes in favor of each Lender according to its Term A Loan

- (i) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;
- (j) a landlord's consent executed in favor of Collateral Agent in respect of all of Borrower's and each Subsidiaries' leased locations;
- (k) a bailee waiver executed in favor of Collateral Agent in respect of each third party bailee where Borrower or any Subsidiary maintains Collateral having a book value in excess of One Hundred Thousand Dollars (\$100,000.00);
  - (l) a duly executed legal opinion of counsel to Borrower dated as of the Effective Date;
- (m) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Lenders; and
  - (n) payment of the fees (if any) and Lenders' Expenses then due as specified in Section 2.5 hereof.
- **3.2 Conditions Precedent to all Credit Extensions.** The obligation of each Lender to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:
  - (a) receipt by Collateral Agent of an executed Disbursement Letter in the form of Exhibit B attached hereto;
- (b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the date of the Disbursement Letter and on the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in Section 5 hereof are true, accurate and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by

materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date;

- (c) in such Lender's sole but reasonable discretion, there has not been any Material Adverse Change or any material adverse deviation by Borrower from the then applicable Annual Projections of Borrower;
- (d) to the extent not delivered at the Effective Date, duly executed original Secured Promissory Notes, in number, form and content acceptable to each Lender, and in favor of each Lender according to its Commitment Percentage, with respect to each Credit Extension made by such Lender after the Effective Date; and
  - (e) payment of the fees (if any) and Lenders' Expenses then due as specified in Section 2.5 hereof.
- **3.3 Covenant to Deliver.** Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Credit Extension. Borrower expressly agrees that a Credit Extension made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Credit Extension in the absence of a required item shall be made in each Lender's sole discretion.
- 3.4 **Procedures for Borrowing.** Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan, Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 2:00 PM Eastern time five (5) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to the Lenders by electronic mail or facsimile a completed Disbursement Letter executed by a Responsible Officer or his or her designee. The Lenders may rely on any telephone notice given by a person whom a Lender reasonably believes is a Responsible Officer or designee. On the Funding Date, each Lender shall credit and/or transfer (as applicable) to the Designated Deposit Account, an amount equal to its Term Loan Commitment.

## 4.CREATION OF SECURITY INTEREST

**4.1 Grant of Security Interest.** Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral (other than Permitted Liens of the type described in clause (c) of the definition of Permitted Liens or other Permitted Liens of the types described in clauses (b), (d), (e), (f), (h), (k) and (l) of the definition of Permitted Liens that have priority to the Collateral Agent's security interest by operation of law). If Borrower shall acquire a commercial tort claim (as defined in the Code) with a value in excess of Fifty Thousand Dollars (\$50,000), Borrower shall promptly notify Collateral Agent in a writing signed by Borrower, as the case may be, of the general details thereof (and further details as may be required by Collateral Agent) and grant to Collateral Agent, for the ratable benefit of the Lenders, in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to make Credit Extensions has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower.

**4.2 Authorization to File Financing Statements.** Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents, including a notice that any disposition of the Collateral, except to the extent permitted by

the terms of this Agreement, by Borrower, or any other Person, shall be deemed to violate the rights of Collateral Agent under the Code.

**4.3 Pledge of Collateral.** Borrower hereby pledges, assigns and grants to Collateral Agent, for the ratable benefit of the Lenders, a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. On the Effective Date, or, to the extent not certificated as of the Effective Date, within fifteen (15) days of the certification of any Shares, the certificate or certificates for the Shares will be delivered to Collateral Agent, accompanied by an instrument of assignment duly executed in blank by Borrower. To the extent required by the terms and conditions governing the Shares, Borrower shall cause the books of each entity whose Shares are part of the Collateral and any transfer agent to reflect the pledge of the Shares. Upon the occurrence and during the continuance of an Event of Default hereunder, Collateral Agent may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Collateral Agent and cause new (as applicable) certificates representing such securities to be issued in the name of Collateral Agent or its transferee. Borrower will execute and deliver such documents, and take or cause to be taken such actions, as Collateral Agent may reasonably request to perfect or continue the perfection of Collateral Agent's security interest in the Shares. Unless an Event of Default shall have occurred and be continuing, Borrower shall be entitled to exercise any voting rights with respect to the Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violati

## **5.REPRESENTATIONS AND WARRANTIES**

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

Due Organization, Authorization: Power and Authority. Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate signed by an officer of Borrower or such Subsidiary (each a "Perfection Certificate" and collectively, the "Perfection Certificates"). Borrower represents and warrants that (a) Borrower and each of its Subsidiaries' exact legal name is that which is indicated on its respective Perfection Certificate and on the signature page of each Loan Document to which it is a party; (b) Borrower and each of its Subsidiaries is an organization of the type and is organized in the jurisdiction set forth on its respective Perfection Certificate; (c) each Perfection Certificate accurately sets forth each of Borrower's and its Subsidiaries' organizational identification number or accurately states that Borrower or such Subsidiary has none; (d) each Perfection Certificate accurately sets forth Borrower's and each of its Subsidiaries' place of business, or, if more than one, its chief executive office as well as Borrower's and each of its Subsidiaries' mailing address (if different than its chief executive office); (e) Borrower and each of its Subsidiaries (and each of its respective predecessors) have not, in the past five (5) years, changed its jurisdiction of organization, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries, is accurate and complete in all material respects (it being understood and agreed that Borrower and each of its Subsidiaries may from time to time update certain information in the Perfection Certificates (including the information set forth in clause (d) above) after the Effective Date to the extent permitted by one or more specific provisions in this Agreement); such updated Perfection Certificates subject to the review and approval of Collateral Agent. If Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, Borrower shall notify Collateral Agent of such occurrence and provide Collateral Agent with such Person's organizational identification number within five (5) Business Days of receiving such organizational identification number.

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's or such Subsidiaries' organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a

default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect or are being obtained pursuant to Section 6.1(b)), or (v) constitute an event of default under any material agreement by which Borrower or any of such Subsidiaries, or their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

## 5.2 Collateral.

- (a) Borrower and each of its Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith (as the same may be updated from time to time in accordance with Section 6.6) with respect of which Borrower or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein. The Accounts are bona fide, existing obligations of the Account Debtors.
- (b) On the Effective Date, and except as disclosed on the Perfection Certificate (i) the Collateral is not in the possession of any third party bailee (such as a warehouse), and (ii) no such third party bailee possesses components of the Collateral in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00). None of the components of the Collateral valued in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00) in the aggregate shall be maintained at locations other than as disclosed in the Perfection Certificates on the Effective Date or as permitted pursuant to Section 6.11.
- (c) All Inventory is in all material respects of good and marketable quality, free from material defects, other than drug product prior to release by quality assurance or following the expiration date.
- (d) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Perfection Certificates or otherwise notified to Collateral Agent pursuant to the terms of this Agreement (to the extent Borrower is permitted to take such action resulting in the applicable update by one or more specific provisions of this Agreement), neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other material agreement with respect to which Borrower or such Subsidiary is the licensee that (i) prohibits or otherwise restricts Borrower or its Subsidiaries from granting a security interest in Borrower's or such Subsidiaries' interest in such material license or material agreement or any other material property, or (ii) for which a default under or termination of could reasonably be expected to interfere with Collateral Agent's or any Lender's right to sell any Collateral. Borrower shall provide written notice to Collateral Agent and each Lender within fifteen (15) days of Borrower or any of its Subsidiaries entering into or becoming bound by any material license or material agreement with respect to which Borrower or any Subsidiary is the licensee (other than (x) over-the-counter software or cell lines that are commercially available to the public and (y) licenses which are subject to the immediately preceding sentence).
- **5.3 Litigation.** Except as disclosed (i) on the Perfection Certificates, or (ii) in accordance with Section 6.9 hereof, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries which could reasonably be expected to result in damage or costs to Borrower or such Subsidiaries in excess of more than Two Hundred Fifty Thousand Dollars (\$250,000.00).
- **5.4 No Material Deterioration in Financial Condition; Financial Statements.** All consolidated financial statements for Borrower and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP (subject, in the case of unaudited financial statements, to normal year-end non-cash adjustments, consistent with Borrower's past practices), in all material respects, as of the dates and for the time periods presented therein, the

consolidated financial condition of Borrower and its Subsidiaries, and the consolidated results of operations of Borrower and its Subsidiaries. There has not been any material deterioration in the financial condition of Borrower and its Subsidiaries, on a consolidated basis, since the date of the most recent financial statements submitted to any Lender.

- **5.5 Solvency.** Borrower is Solvent, and Borrower and its Subsidiaries, on a consolidated basis, are Solvent.
- **5.6 Regulatory Compliance.** Neither Borrower nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower's nor any of its Subsidiaries' properties or assets has been used by Borrower or such Subsidiary or, to Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

- **5.7 Investments.** Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.
- Tax Returns and Payments; Pension Contributions. Borrower and each of its Subsidiaries has timely filed (or timely filed extensions to file) all required Tax returns and reports (or, in the case of Tax returns and reports which are not for federal taxes, all required material Tax returns and reports), and Borrower and each of its Subsidiaries, has timely paid all material foreign, federal, material state, and material local Taxes, assessments, deposits and contributions owed by Borrower and such Subsidiaries, in all jurisdictions in which Borrower or any such Subsidiary is subject to Taxes, including the United States, unless (a) such Taxes are being contested in accordance with the following sentence or (b) in the case of non-federal material Tax returns and reports, material foreign, material state or material local Taxes, if such non-federal material Tax returns and reports, material foreign, material state or material local Taxes, assessments, deposits and contributions do not, individually or in the aggregate, exceed Twenty Thousand Dollars (\$20,000.00). Borrower and each of its Subsidiaries, may defer payment of any contested Taxes, provided that Borrower or such Subsidiary, (a) in good faith contests its obligation to pay the Taxes by appropriate proceedings promptly and diligently instituted and conducted, (b) notifies Collateral Agent in writing of the commencement of, and any material development in, the proceedings, and (c) posts bonds or takes any other steps required to prevent the Governmental Authority levying such contested Taxes from obtaining a Lien upon any of the Collateral that is other than a "Permitted Lien." Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed in writing for any of Borrower's or such Subsidiaries', prior Tax years which could result in additional Taxes in excess of Twenty Thousand Dollars (\$20,000.00) becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or

permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

- **5.9 Use of Proceeds.** Borrower shall use the proceeds of the Credit Extensions solely as working capital and to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.
- **5.10 Shares.** Borrower has full power and authority to create a first lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.
- **5.11 Full Disclosure.** No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading in light of the circumstances under which such statements were made, after giving effect to all supplements and updates thereto from time to time (it being recognized that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).
- **1.1 Definition of "Knowledge."** For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

### **6.AFFIRMATIVE COVENANTS**

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

## 6.1 Government Compliance.

- (a) Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.
- (b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Lenders, in all of the Collateral. Upon Collateral Agent's reasonable request, Borrower shall promptly provide copies to Collateral Agent of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries

## 6.2 Financial Statements, Reports, Certificates.

(a) Deliver to each Lender:

(i) no later than forty-five (45) days after the last day of each fiscal quarter, a company prepared consolidated and consolidating balance sheet, income statement and cash flow statement covering the

consolidated operations of Borrower and its Subsidiaries for such fiscal quarter certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent;		
(ii) no later than one hundred twenty (120) days after the last day of Borrower's fiscal year or within five (5) days of filing with the SEC, audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion (or an opinion qualified only for going concern explanatory language as it relates to Borrower's cash levels so long as no Event of Default has occurred or is continuing) on the financial statements from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion, provided that certified public accounting firms of recognized national standing shall be acceptable to the Collateral Agent;		
(iii) no later than thirty (30) days after the last day of each of Borrower's fiscal years, Borrower's annual financial projections for the entire current fiscal year as approved by Borrower's Board of Directors, which such annual financial projections shall be set forth in a quarter-by-quarter format (such annual financial projections as originally delivered to Collateral Agent and the Lenders are referred to herein as the " <b>Annual Projections</b> "; provided that, any revisions of the Annual Projections approved by Borrower's Board of Directors shall be delivered to Collateral Agent and the Lenders no later than seven (7) days after such approval);		
(iv) within five (5) Business Days of delivery, copies of all non-ministerial statements, reports and notices made generally available to Borrower's security holders or holders of Subordinated Debt;		
(v) within five (5) Business Days of filing, all reports on Form 10-K, 10-Q and 8-K filed with the Securities and Exchange Commission;		
(vi) within five (5) days after the fact, in the event that Borrower is no longer subject to the reporting requirements under the Securities Exchange Act of 1934, as amended, notice of (x) any material changes to the capitalization table of Borrower and (y) any non-ministerial amendments or changes to the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting		

(vii) prompt notice of any event that could reasonably be expected to materially and adversely affect the Intellectual Property in a manner that could have a material and adverse effect on Borrower's business as conducted;

such amendments or changes with respect thereto;

(viii) no later than thirty (30) days after the last day of each month with respect to deposit accounts or last day of each quarter with respect to securities accounts, copies of the month-end or quarter-end, as applicable, account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s); and

other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

- (b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than forty-five (45) days after the last day of each fiscal quarter, deliver to each Lender, a duly completed Compliance Certificate signed by a Responsible Officer.
- (c) Keep proper books of record and account in accordance with GAAP in all material respects (subject to normal year-end non-cash adjustments, consistent with Borrower's past practices), in which full, true and correct entries shall be made of all dealings and transactions in relation to its business and activities. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during

regular business hours upon reasonable prior notice (but not less than five (5) days prior written notice) (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than once every year unless (and more frequently if) an Event of Default has occurred and is continuing.

- **6.3 Inventory; Returns.** Keep all Inventory in good and marketable condition, free from material defects, other than drug product prior to release by quality assurance or following the expiration date. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, customary practices as they exist at the Effective Date. Borrower must promptly notify Collateral Agent and the Lenders of all returns, recoveries, disputes and claims that involve Inventory with a book value of more than One Hundred Thousand Dollars (\$100,000.00) individually or in the aggregate in any calendar year.
- **Taxes; Pensions.** Timely file and require each of its Subsidiaries to timely file, all required Tax returns and reports (or, in the case of Tax returns and reports which are not for federal taxes, all required material Tax returns and reports) and timely pay, and require each of its Subsidiaries to timely pay, all material foreign, federal, material state, and material local Taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except for deferred payment of any Taxes contested pursuant to the terms of Section 5.8 hereof, and shall deliver to Lenders, on demand, appropriate certificates attesting to such payments (or contested payments), and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans; provided that, as used herein, "material foreign, material Tax returns and reports, material state, and material local Taxes, assessments, deposits and contributions" mean those, individually or in the aggregate, equal to or exceed Twenty Thousand Dollars (\$20,000.00).
- Insurance. Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent. Subject to the Post Closing Letter, all property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent, as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, subject to the Post Closing Letter, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days prior written notice before any such policy or policies shall be materially altered or canceled. At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to Five Hundred Thousand Dollars (\$500,000.00) with respect to any loss, but not exceeding Five Hundred Thousand Dollars (\$500,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent may make, at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent deems prudent.

## 6.6 Operating Accounts.

(a) Maintain all of Borrower's and its Subsidiaries' Collateral Accounts at the banks and financial institutions as disclosed in the Perfection Certificates delivered on the Effective Date (if Borrower desires to establish a Collateral Account with any bank or financial institution that is not disclosed in the Perfection Certificate delivered on the Effective Date, such Person shall be acceptable to Collateral Agent in its reasonable discretion (except for a

new Excluded Account as Collateral Agent will not need to approve the bank or financial institution at which such new Excluded Account is maintained) and Borrower shall be in compliance with the requirements of Section 6.6(b)); provided that, such Collateral Accounts, which are held by Borrower or a Guarantor, other than the Excluded Accounts, are at all times subject to a Control Agreement or other appropriate instrument under applicable law in favor of Collateral Agent with respect to any such Collateral Accounts to perfect Collateral Agent's Lien in such Collateral Accounts in accordance with the terms hereunder and provide Collateral Agent with the ability to assert control with respect thereto.

- (b) Borrower shall provide Collateral Agent five (5) days' prior written notice before Borrower or any of its Subsidiaries establishes any Collateral Account, other than Excluded Accounts, at or with any Person following the Effective Date. In addition, for each Collateral Account that Borrower or any Guarantor, at any time maintains, Borrower or such Subsidiary shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument under applicable law with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account in accordance with the terms hereunder and provide Collateral Agent with the ability to assert control with respect thereto prior to the establishment of such Collateral Account, which Control Agreement or other appropriate instrument under applicable law may not be terminated without prior written consent of Collateral Agent. The provisions of the previous sentence shall not apply to Excluded Accounts.
- (c) Neither Borrower nor any of its Subsidiaries shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with Sections 6.6(a) and (b).
- **6.7 Protection of Intellectual Property Rights.** Borrower and each of its Subsidiaries shall: (a) use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its owned Intellectual Property that is material to Borrower's business as conducted; (b) promptly upon becoming aware, advise Collateral Agent in writing of material infringement by a third party of its owned Intellectual Property that is material to Borrower's business as conducted; and (c) not allow any owned Intellectual Property material to Borrower's business as conducted to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent.
- **6.8 Litigation Cooperation.** Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, upon reasonable request and during regular business hours (unless an Event of Default has occurred and is continuing), without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower. In such event, Collateral Agent shall work cooperatively with Borrower to minimize disruption, to the extent reasonably possible, of Borrower's ongoing operations.
- **6.9 Notices of Litigation and Default.** Borrower will give prompt written notice to Collateral Agent and the Lenders of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of Two Hundred Fifty Thousand Dollars (\$250,000.00) or more or which could reasonably be expected to have a Material Adverse Change. Without limiting or contradicting any other more specific provision of this Agreement, promptly (and in any event within three (3) Business Days) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, Borrower shall give written notice to Collateral Agent and the Lenders of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default.

## 6.10 Intentionally Omitted.

**6.11 Landlord Waivers; Bailee Waivers.** In the event that Borrower or any of its Subsidiaries, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then Borrower or such Subsidiary will first notify Collateral Agent and, in the event that the new location is the chief

executive office of the Borrower or such Subsidiary or the Collateral at any such new location is valued in excess of One Hundred Thousand Dollars (\$100,000.00) in the aggregate, such bailee or landlord, as applicable, must execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be.

**6.12 Creation/Acquisition of Subsidiaries.** In the event Borrower, or any of its Subsidiaries creates or acquires any Subsidiary (including, without limitation, pursuant to a Division), Borrower shall provide prior written notice to Collateral Agent and each Lender of the creation or acquisition of such new Subsidiary and take all such action as may be reasonably required by Collateral Agent or any Lender to cause each such Subsidiary to become a co-Borrower hereunder or to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the assets of such Subsidiary (substantially as described on Exhibit A hereto); and Borrower (or its Subsidiary, as applicable) shall grant and pledge to Collateral Agent, for the ratable benefit of the Lenders, a perfected security interest in the Shares of each such newly created Subsidiary (subject to the limitations in the definition of Shares); provided, however, that solely in the circumstance in which Borrower or any Subsidiary creates or acquires a Foreign Subsidiary (excluding, for the sake of clarity, Kezar Australia) in an acquisition permitted by Sections 7.3 or 7.7 hereof or otherwise approved by the Required Lenders, such Foreign Subsidiary shall not be required to guarantee the Obligations of Borrower under the Loan Documents and grant a continuing pledge and security interest in and to the assets of such Foreign Subsidiary.

### **6.13** Further Assurances.

- (a) Execute any further instruments and take further action as Collateral Agent reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.
- (b) Deliver to Collateral Agent and Lenders, within five (5) days after the same are sent or received, copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or otherwise could reasonably be expected to have a Material Adverse Change.

## **7.NEGATIVE COVENANTS**

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

- **7.1 Dispositions.** Convey, sell, lease, transfer, assign, or otherwise dispose of (including, without limitation, pursuant to a Division) (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn out, surplus or obsolete Inventory or Equipment; (c) in connection with Permitted Liens, Permitted Investments and Permitted Licenses; or (d) consisting of Borrower's use or transfer of money or Cash Equivalents in connection with transactions not prohibited hereunder, in the ordinary course of business, and consistent with the then applicable Annual Projections.
- **Changes in Business, Management, Ownership, or Business Locations.** (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve; or (c) (i) any Key Person shall cease to be actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent within ten (10) days after such change, or (ii) enter into any transaction or series of related transactions in which the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than forty nine percent (49%) of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions (other than by the sale of Borrower's equity securities in a public offering, a private placement of public equity or to venture capital investors so long as Borrower identifies to Collateral Agent the venture capital investors prior to the closing of the transaction). Borrower shall not, without at least fifteen (15) Business Days' prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations (i) contain less than One Hundred Thousand Dollars (\$100,000.00) in assets or property of Borrower or any of its Subsidiaries and (ii) are not Borrower's or its Subsidiaries' chief executive office); (B) change

its jurisdiction of organization, (C) change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization.

- **7.3 Mergers or Acquisitions.** Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person (including, without limitation, pursuant to a Division). A Subsidiary may merge or consolidate into another Subsidiary (provided such surviving Subsidiary is a "co-Borrower" hereunder or has provided a secured Guaranty of Borrower's Obligations hereunder) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default has occurred (which has not been waived by Collateral Agent and the Lenders in their sole discretion or otherwise cured by Borrower as expressly permitted in accordance with this Agreement) or arises as a result therefrom.
- **7.4 Indebtedness.** Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.
- **7.5 Encumbrance.** Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (other than Permitted Liens of the type described in clause (c) of the definition of Permitted Liens or other Permitted Liens of the types described in clauses (b), (d), (e), (f), (h), (k) and (l) of the definition of Permitted Liens that have priority to the Collateral Agent's security interest by operation of law), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of "**Permitted Liens**" herein.
  - 7.6 Maintenance of Collateral Accounts. Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.
- **7.7 Distributions; Investments.** (a) Pay any dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock (other than (i) repurchases pursuant to the terms of employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or similar plans, by the cancellation of indebtedness or otherwise, provided such repurchases do not exceed One Hundred Thousand Dollars (\$100,000.00) in the aggregate per fiscal year, (ii) conversions of any of its convertible securities into other securities pursuant to the terms of such convertible securities or otherwise in exchange thereof, and (iii) dividends or distributions by any Subsidiary of Borrower to Borrower) or (b) directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so.
- **7.8 Transactions with Affiliates.** Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries, and (c) transactions between Borrower and any Subsidiaries of Borrower otherwise permitted by the terms of this Agreement.
- **7.9 Subordinated Debt.** (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof, except in accordance with the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or adversely affect the subordination thereof to Obligations owed to the Lenders.
- **7.10 Compliance.** Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the

Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to meet the minimum funding requirements of ERISA, or permit a Reportable Event (as described in Section 4043 of ERISA, and for which the 30 day notice requirement has not been waived) or a non-exempt Prohibited Transaction, as defined in Section 406 of ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

- 7.11 Compliance with Anti-Terrorism Laws. Collateral Agent hereby notifies Borrower and each of its Subsidiaries that pursuant to the requirements of Anti-Terrorism Laws, and Collateral Agent's policies and practices, Collateral Agent is required to obtain, verify and record certain information and documentation that identifies Borrower and each of its Subsidiaries and their principals, which information includes the name and address of Borrower and each of its Subsidiaries and such other information that will allow Collateral Agent to identify such party in accordance with Anti-Terrorism Laws. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate under the control of Borrower or such Subsidiary to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Borrower and each of its Subsidiaries shall immediately notify Collateral Agent if Borrower or such Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attemp
- **7.12 Foreign Subsidiary Assets.** (a) Permit the aggregate amount of cash and the value of assets held or maintained by Kezar Australia to exceed Two Million Dollars (\$2,000,000) at any time, (b) permit Kezar Australia to own or license any Intellectual Property other than Permitted Licenses or (c) permit any Foreign Subsidiary (other than Kezar Australia) which is not a Borrower or Guarantor hereunder to (x) own or license hold any Intellectual Property other than Permitted Licenses or (y) hold, maintain or own any other material assets other than Permitted Investments.

## **8.EVENTS OF DEFAULT**

Any one of the following shall constitute an event of default (an "Event of Default") under this Agreement:

**8.1 Payment Default.** Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof). During the cure period, the failure to cure the payment default is not an Event of Default (but no Credit Extension will be made during the cure period);

## 8.2 Covenant Default.

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Notice of Litigation and Default), 6.11 (Landlord Waivers; Bailee Waivers), 6.12 (Creation/Acquisition of Subsidiaries) or 6.13 (Further Assurances) or Borrower violates any covenant in Section 7; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within ten (10) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Grace periods provided under this Section shall not apply, among other things, to financial covenants or any other covenants set forth in subsection (a) above;

## **8.3 Material Adverse Change.** A Material Adverse Change occurs;

### 8.4 Attachment; Levy; Restraint on Business.

- (a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any Lender or any Lender's Affiliate or any bank or other institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, in excess of Fifty Thousand Dollars (\$50,000.00), or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets, in excess of Fifty Thousand Dollars (\$50,000.00), by any government agency, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; and
- (b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;
- **8.5 Insolvency.** (a) Borrower or any of its Subsidiaries is or becomes Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Credit Extensions shall be made while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);
- **8.6 Other Agreements.** There is a default in any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of Five Hundred Thousand Dollars (\$500,000.00) or that could reasonably be expected to have a Material Adverse Change; provided, however, that the Event of Default under this Section 8.6 caused by the occurrence of a breach or default under such other agreement shall be cured or waived for purposes of this Agreement upon Collateral Agent receiving written notice from the party asserting such breach or default of such cure or waiver of the breach or default under such other agreement, if at the time of such cure or waiver under such other agreement (x) Collateral Agent has not declared an Event of Default under this Agreement and/or exercised any rights with respect thereto; (y) any such cure or waiver does not result in an Event of Default under any other provision of this Agreement or any Loan Document; and (z) in connection with any such cure or waiver under such other agreement, the terms of any agreement with such third party are not modified or amended in any manner which could in the good faith business judgment of Collateral Agent be materially less advantageous to Borrower or any Guarantor;
- **8.7 Judgments.** One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Five Hundred Thousand Dollars (\$500,000.00) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof (provided that no Credit Extensions will be made prior to the satisfaction, vacation, or stay of such judgment, order or decree);
- **8.8 Misrepresentations.** Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan

Document or in any writing delivered to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made;

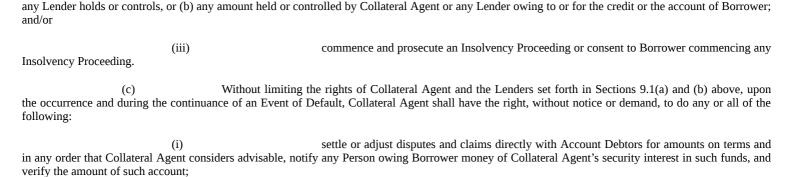
- **8.9 Subordinated Debt.** A default or breach occurs under any agreement between Borrower or any of its Subsidiaries and any creditor of Borrower or any of its Subsidiaries that signed a subordination, intercreditor, or other similar agreement with Collateral Agent or the Lenders, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;
- **8.10 Guaranty.** (a) Any Guaranty terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any Guaranty; (c) any circumstance described in Sections 8.3, 8.4, 8.5, 8.7, or 8.8 occurs with respect to any Guarantor, or (d) the liquidation, winding up, or termination of existence of any Guarantor;
- **8.11 Governmental Approvals.** Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term and such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or
- **8.12 Lien Priority**. Any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien (other than Permitted Liens of the type described in clause (c) of the definition of Permitted Liens or other Permitted Liens of the types described in clauses (b), (d), (e), (f), (h), (k) and (l) of the definition of Permitted Liens that have priority to the Collateral Agent's security interest by operation of law); provided that such circumstance is not solely due to Collateral Agent's failure to file an appropriate continuation financing statement, amendment financing statement or initial financing statement.
- **8.13 Delisting.** The shares of common stock of Borrower are delisted from NASDAQ Capital Market because of failure to comply with continued listing standards thereof or due to a voluntary delisting which results in such shares not being listed on any other nationally recognized stock exchange in the United States having listing standards at least as restrictive as the NASDAQ Capital Market.

## 9.RIGHTS AND REMEDIES

## 9.1 Rights and Remedies.

- (a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, and at the written direction of Required Lenders shall, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).
- (b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;



apply to the Obligations any (a) balances and deposits of Borrower that Collateral Agent or

- (ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Collateral Agent requests and make it available in a location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;
- (iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. Collateral Agent is hereby granted a limited non-exclusive, non sub-licensable, royalty-free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, solely to the extent necessary in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;
- (iv) place a "hold" on any account maintained with Collateral Agent or the Lenders and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;
  - (v) demand and receive possession of Borrower's Books;
- (vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and
- (vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance. As used in the immediately preceding sentence, "Exigent Circumstance" means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

- **9.2 Power of Attorney.** Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney-in-fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make Credit Extensions hereunder. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide Credit Extensions terminates.
- **9.3 Protective Payments.** If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.
- Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other indebtedness or obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to Pro Rata Share unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's portion of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its ratable share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its ratable share, then the portion of such payment or distribution in excess of such Lender's ratable share shall be received by such Lender in trust for and shall be promptly paid over to the

other Lender for application to the payments of amounts due on the other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for Collateral Agent and other Lenders for purposes of perfecting Collateral Agent's security interest therein.

- **9.5 Liability for Collateral.** So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.
- **9.6 No Waiver; Remedies Cumulative.** Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.
- **9.7 Demand Waiver.** Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

## 10.NOTICES

All notices, consents, requests, approvals, demands, or other communication (collectively, "Communication") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile (for notices sent to Collateral Agent) or electronic mail transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number (for notices sent to Collateral Agent), or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address, facsimile number (for notices sent to Collateral Agent), or email address by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower: KEZAR LIFE SCIENCES, INC.

4000 Shoreline Court, Suite 300 South San Francisco, CA 94080 Attn: Marc L. Belsky, CFO

Email: mbelsky@kezarbio.com

with a copy (which shall not

constitute notice) to:

Cooley LLP

1299 Pennsylvania Avenue, NW,

Suite 700

Washington, DC 20004-2400Attn: Jaime L. Chase

Email: jchase@cooley.com

If to Collateral Agent:

OXFORD FINANCE LLC 115 South Union Street

Suite 300

Alexandria, VA 22314 Attention: Legal Department Fax: (703) 519-5225

Email: LegalDepartment@oxfordfinance.com

with a copy (which shall not

constitute notice) to:

DLA PIPER LLP (US) 500 8th Street, NW Washington, DC 20004 Attn: Eric Eisenberg Fax: (202) 799-5211

Email: eric.eisenberg@dlapiper.com

### 11.CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER, AND JUDICIAL REFERENCE

California law governs the Loan Documents without regard to principles of conflicts of law. Borrower, Collateral Agent and each Lender each submit to the exclusive jurisdiction of the State and Federal courts in Santa Clara County, California; provided, however, that nothing in this Agreement shall be deemed to operate to preclude Collateral Agent or any Lender from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of Collateral Agent or any Lender. Borrower expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER, COLLATERAL AGENT AND EACH LENDER EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR EACH PARTY TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES' AGREEMENT TO WAIVE THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY, if the above waiver of the right to a trial by jury is not enforceable, the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties (or, if they cannot agree, by the Presiding Judge of the Santa Clara County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a jury, in Santa Clara County, California; and the parties hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure §§ 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and permanent injunctions and appointing receivers. All such proceedings shall be closed to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the Santa Clara County, California Superior Court for such relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings. The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The private judge shall oversee discovery and may enforce all discovery rules and orders applicable to judicial proceedings in the same manner as a trial court judge. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to California Code of Civil Procedure § 644(a). Nothing in this paragraph shall limit the right of any party at any time to exercise self-help remedies, foreclose against collateral, or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this paragraph.

## **12.GENERAL PROVISIONS**

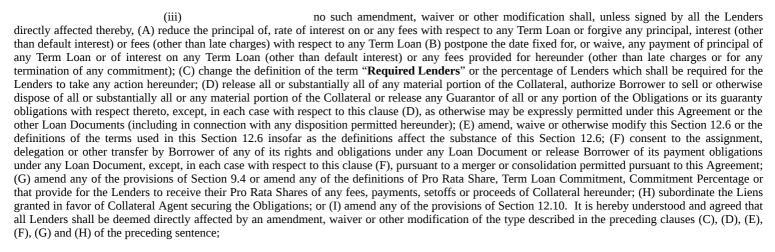
## 12.1 Successors and Assigns.

This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's and each Lender's prior written consent (which may be granted or withheld in Collateral Agent's and each Lender's discretion, subject to Section 12.6). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "Lender Transfer") all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents to any Person; provided, however, that any such Lender Transfer (other than a transfer, pledge, sale or assignment to an Eligible Assignee) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of the Required Lenders (such approved assignee, an "Approved Lender"). Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender as Collateral Agent reasonably shall require. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) sha

(b) The Collateral Agent, acting as a non-fiduciary agent of Borrower (solely for Tax purposes), shall maintain (a) a copy (or electronic equivalent) of the documentation for each Lender Transfer delivered to it, and (b) a register for recordation of the names, addresses, Term Loan Commitments of and Obligations owing to, each Lender. Entries in the register shall be conclusive, absent manifest error, and Borrower, Agent and Lenders shall treat each Person recorded in such register as a Lender for all purposes under the Loan Documents, notwithstanding any notice

to the contrary. The register shall be available for inspection by Borrower or any Lender, from time to time upon reasonable notice.

- (c) Each Lender that sells a participation shall, acting as a non-fiduciary agent of Borrower (solely for Tax purposes), maintain a register in which it enters the participant's name, address and interest in Term Loan Commitments and Obligations (the "Participant Register"). Entries in the Participant Register shall be conclusive, absent manifest error, and such Lender shall treat each Person recorded in the register as the owner of the participation for all purposes, notwithstanding any notice to the contrary. No Lender shall have an obligation to disclose any information in such Participant Register, except to the extent necessary to establish that a participant's interest is in registered form under the IRC and Section 5f.103-1(c) of the U.S. Treasury Regulations. Collateral Agent (in its capacity as Collateral Agent) shall have no responsibility for maintaining a Participant Register.
- Indemnification. Borrower agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an "Indemnified Person") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "Claims") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable documented out-of-pocket attorneys' fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct. This Section 12.2 shall not apply with respect to Taxes to the extent such Taxes obligate Borrower to increase any payment hereunder pursuant to the provisions of Section 2.6 hereof (disregarding, for this purpose, the last sentence of Section 2.6).
  - **12.3 Time of Essence.** Time is of the essence for the performance of all Obligations in this Agreement.
- **12.4 Severability of Provisions.** Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.
- 12.5 Correction of Loan Documents. Collateral Agent and the Lenders may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties, so long as Collateral Agent and the Lenders endeavor to provide Borrower with written notice of such correction.
- **12.6 Amendments in Writing; Integration.** No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:
- (i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;
- (ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature;



- (iv) the provisions of the foregoing clauses (i), (ii) and (iii) are subject to the provisions of any interlender or agency agreement among the Lenders and Collateral Agent pursuant to which any Lender may agree to give its consent in connection with any amendment, waiver or modification of the Loan Documents only in the event of the unanimous agreement of all Lenders.
- (b) Other than as expressly provided for in Section 12.6(a)(i)-(iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.
- (c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.
- **12.7 Counterparts.** This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.
- 12.8 Survival. All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.9 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.
- 12.9 Confidentiality. In handling any confidential information of Borrower, the Lenders and Collateral Agent shall maintain the confidentiality of such information and exercise the same degree of care that it exercises for their own proprietary information, which will be no less than reasonable care, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, or in connection with a Lender's own financing or securitization transactions and upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Credit Extensions (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance

of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement with the Lenders and Collateral Agent with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.9 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.9.

- **12.10 Public Announcement.** With Borrower's prior written consent (such consent not to be unreasonably withheld or delayed), Collateral Agent and each Lender may make a public announcement of the transactions contemplated by this Agreement, and may publicize the same on its company website, in marketing materials, newspapers and other publications, and otherwise, and in connection therewith may use Borrower's name, tradenames, logos, and any information related to the transactions to the extent such information is not confidential.
- 12.11 Right of Set Off. Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.
- **12.12** Cooperation of Borrower. If necessary, Borrower agrees to (i) execute any documents (including new Secured Promissory Notes) reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment or Term Loan to an assignee in accordance with Section 12.1, (ii) upon reasonable written request and during regular business hours, make Borrower's management available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments or Credit Extensions (which meetings shall be conducted no more often than once every twelve months unless an Event of Default has occurred and is continuing), and (iii) use commercially reasonable efforts to assist Collateral Agent or the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment or Term Loan reasonably may request. Subject to the provisions of Section 12.9, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment, any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower prior to entering into this Agreement.
- **12.13 Headings**. Section headings herein and in other Loan Documents are included for convenience of reference only and shall not affect the interpretation of this Agreement or any other Loan Document.

## **13.DEFINITIONS**

**13.1 Definitions.** As used in this Agreement, the following terms have the following meanings:

- "Account" is any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.
  - "Account Debtor" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.
- "Affiliate" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.
  - "Agreement" is defined in the preamble hereof.
- "Amortization Date" is January 1, 2025 (the "Original Amortization Date"); provided, however, if Borrower achieves the Interest-Only Extension Milestone before January 1, 2025, then the Amortization Date shall automatically be extended to January 1, 2026.
  - "Annual Projections" is defined in Section 6.2(a).
- "Anti-Terrorism Laws" are any laws relating to terrorism or money laundering, including Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.
- "Approved Fund" is any (i) investment company, fund, trust, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business or (ii) any Person (other than a natural person) which temporarily warehouses loans for any Lender or any entity described in the preceding clause (i) and that, with respect to each of the preceding clauses (i) and (ii), is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender.
  - "Approved Lender" is defined in Section 12.1.
- "Basic Rate" is, with respect to a Term Loan, the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to the greater of (i) seven and ninety-five one-hundredths of one percent (7.95%) and (ii) the sum of seven and eighty-seven hundredths of one percent (7.87%) and the greater of (A) the thirty (30) day U.S. LIBOR rate reported in The Wall Street Journal on the last Business Day of the month that immediately precedes the month in which the interest will accrue, and (B) eight one-hundredths of one percent (0.08%). Notwithstanding the foregoing, the Basic Rate for the Term Loan for the period from the Effective Date through and including November 30, 2021 shall be seven and ninety-five thousand seven hundred fiftieths of one percent (7.95750%). Notwithstanding anything to the contrary herein or in any other Loan Document, upon the occurrence of a LIBOR Transition Event, Collateral Agent may amend this Agreement to replace the Basic Rate with a LIBOR Replacement Rate. Any such amendment with respect to a LIBOR Transition Event will become effective at 5:00 p.m. (Eastern Standard Time) on the tenth (10th) Business Day after Collateral Agent has notified Borrower of such amendment. Any determination, decision or election that may be made by Collateral Agent pursuant hereto will be conclusive and binding absent manifest error and may be made in Collateral Agent's sole discretion and without consent from any other party.

"Blocked Person" is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) a Person that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"Borrower" is defined in the preamble hereof.

"Borrower's Books" are Borrower's or any of its Subsidiaries' books and records including ledgers, federal, and state Tax returns, records regarding Borrower's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"Business Day" is any day that is not a Saturday, Sunday or a day on which Collateral Agent is closed.

"Cash Equivalents" are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., and (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent. For the avoidance of doubt, the direct purchase by Borrower or any of its Subsidiaries of any Auction Rate Securities, or purchasing participations in, or entering into any type of swap or other derivative transaction, or otherwise holding or engaging in any ownership interest in any type of Auction Rate Security by Borrower or any of its Subsidiaries shall be conclusively determined by the Lenders as an ineligible Cash Equivalent, and any such transaction shall expressly violate each other provision of this Agreement governing Permitted Investments. Notwithstanding the foregoing, Cash Equivalents does not include and Borrower, and each of its Subsidiaries, are prohibited from purchasing participations in, entering into any type of swap or other equivalent derivative transaction, or otherwise holding or engaging in any ownership interest in any type of debt instrument, including, without limitation, any corporate or municipal bonds with a long-term nominal maturity for which the interest rate is reset through a dutch auction and more commonly referred to as an auction rate security (each, an "Auction Rate Security").

"CFC" means a "controlled foreign corporation" under Section 957 of the IRC.

"Claims" are defined in Section 12.2.

"Code" is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of California; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of California, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"Collateral" is any and all properties, rights and assets of Borrower described on Exhibit A.

"Collateral Account" is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Subsidiary at any time.

"Collateral Agent" is, Oxford, not in its individual capacity, but solely in its capacity as agent on behalf of and for the benefit of the Lenders.

"Commitment Percentage" is set forth in Schedule 1.1, as amended from time to time.

"Commodity Account" is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"Communication" is defined in Section 10.

"Compliance Certificate" is that certain certificate in the form attached hereto as Exhibit C.

"Contingent Obligation" is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

"Control Agreement" is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a Securities Account or a Commodity Account, Borrower and such Subsidiary, and Collateral Agent pursuant to which Collateral Agent obtains control (within the meaning of the Code) for the benefit of the Lenders over such Deposit Account, Securities Account, or Commodity Account.

"Copyrights" are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

"Credit Extension" is any Term Loan or any other extension of credit by Collateral Agent or Lenders for Borrower's benefit.

"Default Rate" is defined in Section 2.3(b).

"Deposit Account" is any "deposit account" as defined in the Code with such additions to such term as may hereafter be made.

"Designated Deposit Account" is Borrower's deposit account, (x) with respect to Section 2.3(b) account number 3302446446, maintained with Silicon Valley Bank, and (y) with respect to Section 3.4, account number 173103198383, maintained with U.S. Bank, N.A. or as otherwise designated in the relevant Disbursement Letter.

"Disbursement Letter" is that certain form attached hereto as Exhibit B.

"Division" means, in reference to any Person which is an entity, the division of such Person into two (2) or more separate Persons, with the dividing Person either continuing or terminating its existence as part of such division, including, without limitation, as contemplated under Section 18-217 of the Delaware Limited Liability Company Act for limited liability companies formed under Delaware law, or any analogous action taken pursuant to any other applicable law with respect to any corporation, limited liability company, partnership or other entity.

"Dollars," "dollars" and "\$" each mean lawful money of the United States.

**"EDGAR"** means the Securities and Exchange Commission's Electronic Data Gathering, Analysis and Retrieval System or any successor SEC electronic filing system for such purposes.

"Effective Date" is defined in the preamble of this Agreement.

"Eligible Assignee" is (i) a Lender, (ii) an Affiliate of a Lender, (iii) an Approved Fund and (iv) any commercial bank, savings and loan association or savings bank or any other entity which is an "accredited investor" (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans as one of its businesses, including insurance companies, mutual funds, lease financing companies and commercial finance companies, in each case, which either (A) has a rating of BBB or higher from Standard & Poor's Rating Group

and a rating of Baa2 or higher from Moody's Investors Service, Inc. at the date that it becomes a Lender or (B) has total assets in excess of Five Billion Dollars (\$5,000,000,000,000.00), and in each case of clauses (i) through (iv), which, through its applicable lending office, is capable of lending to Borrower without the imposition of any withholding or similar Taxes; provided that notwithstanding the foregoing, "Eligible Assignee" shall not include, unless an Event of Default has occurred and is continuing, (i) Borrower or any of Borrower's Affiliates or Subsidiaries or (ii) a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent. Notwithstanding the foregoing, (x) in connection with assignments by a Lender due to a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party and (y) in connection with a Lender's own financing or securitization transactions, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Collateral Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee as Collateral Agent reasonably shall require.

**"Equipment"** is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"ERISA" is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

"Event of Default" is defined in Section 8.

"Excluded Accounts" are deposit accounts (a) exclusively used for payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any of its Subsidiaries', employees; (b) exclusively used for the purpose of providing letters of credit or cash collateral as security for Borrower's real estate provided that the amount in such account does not exceed the amount permitted by clause (h) of the definition of Permitted Indebtedness; and (c) accounts of Foreign Subsidiaries (which are not a co-Borrower or Guarantor under this Agreement) held outside of the U.S., provided the aggregate balance of all such accounts shall not to exceed One Million Five Hundred Thousand Dollars (\$1,500,000) at any time.

"Federal Reserve Bank of New York's Website" means the website of the Federal Reserve Bank of New York at http://www.newyorkfed.org, or any successor source.

"Final Payment" is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Maturity Date, or (b) the acceleration of any Term Loan, or (c) the prepayment of a Term Loan pursuant to Section 2.2(c) or (d), equal to the original principal amount of such Term Loan being prepaid at such time multiplied by the Final Payment Percentage, payable to Lenders in accordance with their respective Pro Rata Shares.

"Final Payment Percentage" is six and one-half of one percent (6.50%).

"Foreign Subsidiary" is a Subsidiary that is not (i) an entity organized under the laws of the United States or any political subdivision thereof, or (ii) a Foreign Subsidiary Holdco.

"Foreign Subsidiary Holdco" means any Subsidiary substantially all of the assets of which consist of (a) equity interests of one or more CFCs or other entities that are described in this definition (or are treated as consisting of such assets for U.S. federal income tax purposes) and/or (b) any indebtedness or accounts receivable owed by any CFC or other entity that is described in this definition, or treated as owed by any such entity for U.S. federal income tax purposes.

"Funding Date" is any date on which a Credit Extension is made to or on account of Borrower which shall be a Business Day.

"GAAP" is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

"General Intangibles" are all "general intangibles" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other Tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

"Good Faith Deposit" is defined in Section 2.5(d).

"Governmental Approval" is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"Governmental Authority" is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

"Guarantor" is any Person providing a Guaranty in favor of Collateral Agent.

"Guaranty" is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

"Indemnified Person" is defined in Section 12.2.

"Insolvency Proceeding" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

"Insolvent" means not Solvent.

"Intellectual Property" means all of Borrower's or any Subsidiary's right, title and interest in and to the following:

- (a) Copyrights, Trademarks and Patents;
- (b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;

- (c) any and all source code;
- (d) any and all design rights which may be available to Borrower;
- (e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and
  - (f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

"Interest-Only Extension Milestone" means that the Borrower has drawn either the Term C Loan or the Term D Loan prior to the Original Amortization Date.

"Inventory" is all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person's custody or possession or in transit and including any returned goods and any documents of title representing any of the above

"Investment" is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance, or capital contribution to any Person.

"IRC" means the U.S. Internal Revenue Code of 1986, as amended.

"**Key Person**" is each of Borrower's (i) Chief Executive Officer, who is John Fowler as of the Effective Date, (ii) Chief Financial Officer, who is Marc Belsky as of the Effective Date, (iii) President, who is Christopher Kirk as of the Effective Date and (iv) Chief Scientific Officer, who is Christopher Kirk as of the Effective Date.

"Kezar Australia" means Kezar Life Sciences Australia Pty Ltd., an Australian company incorporated under the laws of Australia and a whollyowned Subsidiary of Borrower.

"Lender" is any one of the Lenders.

"Lenders" are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

"Lenders' Expenses" are all reasonable, documented out-of-pocket audit fees and expenses, costs, and expenses (including reasonable and documented out-of-pocket attorneys' fees and expenses, as well as reasonable and documented out-of-pocket appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

**"LIBOR Replacement Rate"** means the sum of: (a) the alternate benchmark rate (which may include SOFR) that has been selected by Collateral Agent giving due consideration to (i) any selection or recommendation of a replacement rate or the mechanism for determining such a rate by the Relevant Governmental Body or (ii) any evolving or then-prevailing market convention for determining a rate of interest as a replacement to the LIBOR rate for U.S. dollar-denominated syndicated credit facilities and (b) the LIBOR Replacement Spread; provided that, if the LIBOR Replacement Rate as so determined would be less than zero, the LIBOR Replacement Rate will be deemed to be zero for the purposes of this Agreement.

**"LIBOR Replacement Spread"** means, with respect to any replacement of the Basic Rate, the spread adjustment, or method for calculating or determining such spread adjustment, (which may be a positive or negative value or zero) that has been selected by Collateral Agent giving due consideration to (i) any selection or recommendation of a spread adjustment, or method for calculating or determining such spread adjustment, for the

replacement of the LIBOR rate by the Relevant Governmental Body or (ii) any evolving or then-prevailing market convention for determining a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of the LIBOR rate for U.S. dollar-denominated syndicated credit facilities at such time.

"LIBOR Transition Event" means the occurrence of one or more of the following events with respect to the LIBOR rate:

- (1) a public statement or publication of information by or on behalf of the administrator of the LIBOR rate announcing that such administrator has ceased or will cease to provide the LIBOR rate, permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide the LIBOR rate;
- (2) a public statement or publication of information by the regulatory supervisor for the administrator of the LIBOR rate, the U.S. Federal Reserve System, an insolvency official with jurisdiction over the administrator for the LIBOR rate, a resolution authority with jurisdiction over the administrator for the LIBOR rate or a court or an entity with similar insolvency or resolution authority over the administrator for the LIBOR rate, which states that the administrator of the LIBOR rate has ceased or will cease to provide the LIBOR rate permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide the LIBOR rate; or
- (3) a public statement or publication of information by the regulatory supervisor for the administrator of the LIBOR rate announcing that the LIBOR rate is no longer representative.
- "Lien" is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.
- "Loan Documents" are, collectively, this Agreement, the Perfection Certificates, each Compliance Certificate, each Disbursement Letter, the Post Closing Letter, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified.
- "Material Adverse Change" is (a) a material impairment in the perfection or priority of Collateral Agent's Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower or any Subsidiary; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

"Maturity Date" is, for each Term Loan, November 1, 2026.

"Obligations" are all of Borrower's obligations to pay when due any debts, principal, interest, Lenders' Expenses, the Prepayment Fee, the Final Payment, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents, or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower's duties under the Loan Documents.

"OFAC" is the U.S. Department of Treasury Office of Foreign Assets Control.

"OFAC Lists" are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"**Operating Documents**" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than

thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"Original Amortization Date" is defined in the definition of Amortization Date.

"Patents" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

"Payment Date" is the first (1st) calendar day of each calendar month, commencing on January 1, 2022.

"Perfection Certificate" and "Perfection Certificates" is defined in Section 5.1.

"Permitted Indebtedness" is:

Documents;	(a)	Borrower's Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan
	(g)	Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s);
	(h)	Subordinated Debt;
	(i)	unsecured Indebtedness to trade creditors incurred in the ordinary course of business;
5		Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred of finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that appropriate of all such Indebtedness does not exceed Fixe Hundred Thousand Dollars (\$500,000,00) at any time and (ii)

- by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Five Hundred Thousand Dollars (\$500,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made); furthermore, notwithstanding anything to the contrary herein and strictly for the purposes of this clause (e) of the definition of Permitted Indebtedness and for no other purpose, any obligations of a Person that are or would have been treated as operating leases or capital leases for purposes of GAAP prior to the issuance by the Financial Accounting Standards Board on February 25, 2016 of an Accounting Standards Update (the "ASU") shall continue to be accounted for as operating leases or capital leases (whether or not such operating lease obligations or capital lease obligations, as applicable, were in effect on such date) notwithstanding the fact that such obligations are required in accordance with the ASU (on a prospective or retroactive basis or otherwise) to be treated as capitalized lease obligations in accordance with GAAP;
- (k) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower's business;
  - (a) Indebtedness that also constitutes a Permitted Investment;
- (b) reimbursement obligations in connection with letters of credit that are secured by cash or cash equivalents and issued on behalf of the Borrower or a Subsidiary thereof for purposes of securing real estate leases in an aggregate principal amount not to exceed One Million Dollars (\$1,000,000.00) at any time; and
- (c) other unsecured Indebtedness not to exceed One Hundred Thousand Dollars (\$100,000.00) in the aggregate at any time;
- (d) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (i) above, provided that the principal amount thereof is not increased or the terms

thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be.

#### "Permitted Investments" are:

- (a) Investments disclosed on the Perfection Certificate(s) and existing on the Effective Date;
- (l) (i) Investments consisting of cash and Cash Equivalents held in Borrower's Collateral Accounts that are maintained in accordance with Section 6.6 of this Agreement, and (ii) any other Investments permitted by Borrower's investment policy, as amended from time to time, provided that any material amendments to such investment policy have been approved in writing by Collateral Agent;
- (m) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;
- (n) Investments consisting of deposit accounts (x) in which Collateral Agent has a perfected security interest or (y) with respect to Excluded Accounts;
  - (o) Investments in connection with Transfers permitted by Section 7.1;
- (p) Investments (i) by Borrower in Kezar Australia not to exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate in any fiscal year and (ii) by Borrower in Subsidiaries (other than Kezar Australia) for the purposes of funding clinical trials in the relevant jurisdictions and costs related thereto not to exceed One Hundred Thousand Dollars (\$100,000.00) in the aggregate in any fiscal year;
- (q) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors; not to exceed One Hundred Thousand Dollars (\$100,000.00) in the aggregate for (i) and (ii) in any fiscal year;
- (r) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;
- (s) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (i) shall not apply to Investments of Borrower in any Subsidiary;
- (t) Investments consisting of payments owing under license agreements with Onyx (Amgen) as in effect on the Effective Date;
- (u) Investments in joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the licensing of technology, which licensing is non-exclusive or, if exclusive constitutes a Permitted License, the development of technology or the providing of technical support; provided, that the aggregate cash portion of all such Investments shall not exceed One Hundred Thousand Dollars (\$100,000.00) in any fiscal year;
  - (e) additional Investments that do not exceed One Hundred Thousand Dollars (\$100,000.00) in the aggregate.

"Permitted Licenses" are (A) licenses of over-the-counter software that is commercially available to the public, (B) non-exclusive intercompany licenses for purposes of conducting clinical trials, (C) non-exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, <u>provided</u>, that, (i) no Event of Default has occurred or is continuing at the time of such license; (ii) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of

any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; and (iii) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower or any of its Subsidiaries are paid to a Deposit Account that is governed by a Control Agreement; and (D) exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business which may be exclusive as to territory only as to discrete geographical areas outside the Unites states and/or may be exclusive in respect other than territory, provided, that, with respect to each such license described in clause (D), (i) no Event of Default has occurred or is continuing at the time of such license; (ii) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; (iii) Borrower delivers ten (10) days' prior written notice and a brief summary of the terms of the proposed license to Collateral Agent and the Lenders and, (iv) Borrower delivers to Collateral Agent and the Lenders copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof, (v) any such license could not result in a legal transfer of title of the licensed property; and (iv) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower or any of its Subsidiaries are paid to a Deposit Account that is governed by a Control Agreement.

#### "Permitted Liens" are:

- (a) Liens existing on the Effective Date and disclosed on the Perfection Certificates or arising under this Agreement and the other Loan Documents;
- (v) Liens for Taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the IRC, and the Treasury Regulations adopted thereunder;
- (w) liens securing Indebtedness permitted under clause (e) of the definition of "**Permitted Indebtedness**," provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;
- (x) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Two Hundred Fifty Thousand Dollars (\$250,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;
- (y) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);
- (z) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), <u>but</u> any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;
- (aa) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

		banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of rower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar counts are maintained in compliance with Section 6.6(b) hereof;
Section 8.4 or 8.7;	(cc)	Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under
	(dd)	Liens consisting of Permitted Licenses;
	(f)	Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of custom duties

(g) Liens on cash or cash equivalents securing obligations permitted under clause (h) of the definition of Permitted Indebtedness.

that are promptly paid on or before the date they become due; and

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"Post Closing Letter" is that certain Post Closing Letter dated as of the Effective Date by and between Collateral Agent and Borrower.

"**Prepayment Fee**" is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

- (i) for a prepayment made on or after the Funding Date of such Term Loan through and including the second anniversary of the Funding Date of such Term Loan, two percent (2.00%) of the principal amount of such Term Loan prepaid;
- (ii) for a prepayment made after the date which is after the second anniversary of the Funding Date of such Term Loan through and including the third anniversary of the Funding Date of such Term Loan, one percent (1.00%) of the principal amount of the Term Loans prepaid; and
- (iii) for a prepayment made after the third anniversary of the Funding Date of such Term Loan and prior to the Maturity Date, no Prepayment Fee shall be applicable.

"**Pro Rata Share**" is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

"Registered Organization" is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

"Relevant Governmental Body" means the Federal Reserve Board and/or the Federal Reserve Bank of New York, or a committee officially endorsed or convened by the Federal Reserve Board and/or the Federal Reserve Bank of New York or any successor thereto.

"Required Lenders" means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an "Original Lender") have not assigned or transferred any of their interests in their Term Loan, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least sixty six percent (66%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or

transferee of an Original Lender's interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

"**Requirement of Law**" is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

"Responsible Officer" is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower acting alone.

"Secured Promissory Note" is defined in Section 2.4.

"Secured Promissory Note Record" is a record maintained by each Lender with respect to the outstanding Obligations owed by Borrower to Lender and credits made thereto.

"Securities Account" is any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

"Shares" is one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or Borrower's Subsidiary, in any Subsidiary; provided that, in the event Borrower, demonstrates to Collateral Agent's reasonable satisfaction, that any Foreign Subsidiary does not satisfy the holding period requirement pursuant to Section 245A and Section 246(c)(5) of the IRC, "Shares" shall mean sixty-five percent (65%) of the total combined voting power of the issued and outstanding voting capital stock, membership units or other securities entitled to vote owned or held of record by Borrower or its Subsidiary in such Foreign Subsidiary.

"SOFR" with respect to any day means the secured overnight financing rate published for such day by the Federal Reserve Bank of New York, as the administrator of the benchmark, (or a successor administrator) on the Federal Reserve Bank of New York's Website.

"Solvent" is, with respect to any Person: the fair salable value of such Person's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person's liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature.

"Subordinated Debt" is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Lenders.

"Subsidiary" is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

"Tax" or "Taxes" means Taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to Tax or penalties applicable thereto).

"Term Loan" is defined in Section 2.2(a)(v) hereof.

"Term A Loan" is defined in Section 2.2(a)(i) hereof.

"Term B Loan" is defined in Section 2.2(a)(ii) hereof.

"Term B Loan Draw Period" is the period commencing on July 1, 2022 and ending on the earlier of (i) December 30, 2022 and (ii) the occurrence of an Event of Default (which has not been waived by Collateral Agent and the Lenders in their sole discretion or otherwise cured by Borrower as expressly permitted in accordance with this Agreement); provided, however, that the Term B Draw Period shall not commence if on July 1, 2022 an Event of Default has occurred and is continuing.

"Term C Loan" is defined in Section 2.2(a)(iii) hereof.

"Term C Loan Draw Period" is the period commencing on the date of the occurrence of the Term C Milestone and ending on the earliest of (i) the date that is nine (9) months after the occurrence of the Term C Milestone, (ii) June 30, 2023 and (iii) the occurrence of an Event of Default (which has not been waived by Collateral Agent and the Lenders in their sole discretion or otherwise cured by Borrower as expressly permitted in accordance with this Agreement); provided, however, that (x) the Term C Draw Period shall not commence if on the date of the occurrence of the Term C Milestone an Event of Default has occurred and is continuing and (y) if Borrower has achieved the Term C Loan Milestone, Borrower may request Collateral Agent and the Lenders consent to a ninety (90) day extension of the dates set forth in subclause (i) and (ii), such consent shall not be unreasonably withheld by Collateral Agent or the Lenders.

"**Term C Milestone**" means Borrower's delivery to Collateral Agent and the Lenders of evidence, satisfactory to Collateral Agent and Lenders in their sole but reasonable discretion, that Borrower has achieved positive topline data in Borrower's MISSION Phase 2 trial sufficient to advance the program into Phase 2(b) or a registration-enabling trial, and as confirmed by Borrower's Board of Directors in written board minutes.

"Term D Loan" is defined in Section 2.2(a)(iv) hereof.

"Term D Loan Draw Period" is the period commencing on the date of the occurrence of the Term D Milestone and ending on the earliest of (i) the date that is nine (9) months after the occurrence of the Term D Milestone, (ii) June 30, 2023 and (iii) the occurrence of an Event of Default (which has not been waived by Collateral Agent and the Lenders in their sole discretion or otherwise cured by Borrower as expressly permitted in accordance with this Agreement); provided, however, that (x) the Term D Draw Period shall not commence if on the date of the occurrence of the Term D Milestone an Event of Default has occurred and is continuing and (y) if Borrower has achieved the Term D Loan Milestone, Borrower may request Collateral Agent and the Lenders consent to a ninety (90) day extension of the dates set forth in subclause (i) and (ii), such consent shall not be unreasonably withheld by Collateral Agent or the Lenders.

"**Term D Milestone**" means Borrower's delivery to Collateral Agent and the Lenders of evidence, satisfactory to Collateral Agent and Lenders in their sole but reasonable discretion, that Borrower has achieved positive topline data in Borrower's PRESIDIO Phase 2 trial sufficient to advance the program into a registration-enabling trial, and as confirmed by Borrower's Board of Directors in written board minutes.

"**Term E Loan**" is defined in Section 2.2(a)(v) hereof.

"Term E Loan Draw Period" is the period commencing on the date of the occurrence of the Term E Milestone and ending on the earliest of (i) the date that is nine (9) months after the occurrence of the Term E Milestone, (ii) December 31, 2023 and (iii) the occurrence of an Event of Default (which has not been waived by Collateral Agent and the Lenders in their sole discretion); provided, however, that (x) the Term E Draw Period shall not commence if on the date of the occurrence of the Term E Milestone an Event of Default has occurred and is continuing and (y) if Borrower has achieved the Term E Loan Milestone, Borrower may request Collateral Agent and the Lenders consent to a ninety (90) day extension of the dates set forth in subclause (i) and (ii), such consent shall not be unreasonably withheld by Collateral Agent or the Lenders.

"**Term E Milestone**" means Borrower's (i) drawing of either the Term C Loan or the Term D Loan and (ii) delivery to Collateral Agent and the Lenders of evidence, satisfactory to Collateral Agent and Lenders in their sole

but reasonable discretion, that Borrower has achieved positive safety and tolerability data from the dose escalation portion of the Phase 1 clinical trial for KZR-261 in oncology indications, sufficient to advance the program into the dose expansion portion of clinical trials, and as confirmed by Borrower's Board of Directors in written board minutes.

"**Term Loan Commitment**" is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on <u>Schedule 1.1</u>. "**Term Loan Commitments**" means the aggregate amount of such commitments of all Lenders, which, shall in no event exceed Fifty Million Dollars (\$50,000,000.00).

"**Trademarks**" means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

"Transfer" is defined in Section 7.1.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

#### **BORROWER:**

KEZAR LIFE SCIENCES, INC.

By <u>/s/ Marc L. Belsky</u> Name: Marc L. Belsky Title: Chief Financial Officer

### COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By <u>/s/ Colette H. Featherly</u> Name: Colette H. Featherly Title: Senior Vice President

[Signature Page to Loan and Security Agreement]

### **SCHEDULE 1.1**

### **Lenders and Commitments**

### Term A Loans

Term A Loan Commitment	Commitment Percentage
\$10,000,000.00	100.00%
\$10,000,000.00	100.00%
	\$10,000,000.00

# Term B Loans

Lender	Term B Loan Commitment*	Commitment Percentage
OXFORD FINANCE LLC	\$10,000,000.00	100.00%
TOTAL	\$10,000,000.00	100.00%

#### Term C Loans

Lender	Term C Loan Commitment*	Commitment Percentage
OXFORD FINANCE LLC	\$20,000,000.00	100.00%
TOTAL	\$20,000,000,00	100.00%

### Term D Loans

Lender	Term D Loan Commitment*	Commitment Percentage
OXFORD FINANCE LLC	\$20,000,000.00	100.00%
TOTAL	\$20,000,000.00	100.00%

#### Term E Loans

Lender	Term E Loan Commitment*	Commitment Percentage
OXFORD FINANCE LLC	\$20,000,000.00	100.00%
TOTAL	\$20,000,000.00	100.00%

### **Aggregate (all Term Loans)**

Lender	Term Loan Commitments	Commitment Percentage
OXFORD FINANCE LLC	\$50,000,000.00	100.00%
TOTAL	\$50,000,000.00	100.00%

Loans funded.	ll equal the lesser of the am		

#### **EXHIBIT A**

#### **Description of Collateral**

The Collateral consists of all of Borrower's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any Intellectual Property, including but not limited to, for the avoidance of doubt, any Intellectual Property licensed to Borrower pursuant to the terms of that certain Exclusive License Agreement, dated as of June 11, 2015, by and between Borrower and Onyx Therapeutics, Inc.; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property; provided further that if a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property solely to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that constitute proceeds of the Intellectual Property; and (ii) more than sixty-five percent (65%) of the total combined voting power of the issued and outstanding voting capital stock, membership units or other securities owned or held of record by Borrower or its Subsidiary in such Foreign Subsidiary, if Borrower demonstrates, to the reasonable satisfaction of Collateral Agent, that such Foreign Subsidiary does not satisfy the holding period requirement pursuant to Section 245A of the IRC; (iii) any license, interest or contract, in each case if the granting of a Lien in such license, interest or contract is prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Borrower has agreed not to encumber any of its Intellectual Property.

# EXHIBIT B

# Form of Disbursement Letter

[see attached]

#### DISBURSEMENT LETTER

November 4, 2021

The undersigned, being the duly elected and acting Chief Financial Officer of KEZAR LIFE SCIENCES, INC., a Delaware corporation with offices located at 4000 Shoreline Court, Suite 300, South San Francisco, CA 94080 ("Borrower"), does hereby certify to OXFORD FINANCE LLC ("Oxford" and "Lender"), as collateral agent (the "Collateral Agent") in connection with that certain Loan and Security Agreement dated as of November 4, 2021, by and among Borrower, Collateral Agent and the Lenders from time to time party thereto (the "Loan Agreement"; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

- 1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects as of the date hereof.
  - 2. No event or condition has occurred that would constitute an Event of Default under the Loan Agreement or any other Loan Document.
  - 3. Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.
- 4. All conditions referred to in Section 3 of the Loan Agreement to the making of the Term Loan to be made on or about the date hereof have been satisfied or waived by Collateral Agent.
  - 5. No Material Adverse Change has occurred.
  - 6. The undersigned is a Responsible Officer.

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7.	The proceeds of the Term [A][B][C][D	D][E] Loan shall be disbursed as follows:	
	<b>Disbursement from Oxford:</b> Loan Amount		\$
	Plus: Deposit Received		\$
	Less: [Interim Interest Lender's Legal Fees		(\$)] (\$)*
	TOTAL TERM [A][B][C][D][E] I	LOAN NET PROCEEDS FROM LENDERS	\$
8.	The Term [A][B][C][D][E] Loan shall	amortize in accordance with the Amortization Table attached hereto.	
9.	The aggregate net proceeds of the Terr	n Loans shall be transferred to the Designated Deposit Account as follo	ws:
	Account Name:	KEZAR LIFE SCIENCES, INC.	
	Bank Name:	[]	
	Bank Address:	[]	
	Account Number:	[]	
	ABA Number:	[]	
		[Balance of Page Intentionally Left Blank]	
* Legal fees a post-closing.	nd costs are through the Effective Date.	Post-closing legal fees and costs, payable after the Effective Date, to b	e invoiced and paid



Dated as of the date first set forth above.
BORROWER:
KEZAR LIFE SCIENCES, INC.
By Name: Title:
COLLATERAL AGENT AND LENDER:
OXFORD FINANCE LLC
By Name: Title:
[Signature Page to Disbursement Letter]

# AMORTIZATION TABLE (Term [A][B][C][D][E] Loan)

[see attached]

### **EXHIBIT C**

# **Compliance Certificate**

TO:	OXFORD FINANCE LLC, as Collateral Agent and Lender
FROM:	KEZAR LIFE SCIENCES, INC.
conditions of	ned authorized officer ("Officer") of KEZAR LIFE SCIENCES, INC. ("Borrower"), hereby certifies that in accordance with the terms and the Loan and Security Agreement by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the "Loan capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),
(a)	Borrower is in complete compliance for the period ending with all required covenants except as noted below;
(b)	There are no Events of Default, except as noted below;
respects on the representation	Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material his date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any s and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and pressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.
Subsidiaries, h	Borrower, and each of Borrower's Subsidiaries, has timely filed all required Tax returns and reports, Borrower, and each of Borrower's nas timely paid all foreign, federal, state, and local Taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as mitted pursuant to the terms of Section 5.8 of the Loan Agreement;
	No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of er has not previously provided written notification to Collateral Agent and the Lenders.
statements are except as expl	he required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next lained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and reend audit adjustments as to the interim financial statements.
Please indicat	te compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.
,	

	Reporting Covenant	Requirement	Actual		Complies	
1)	Financial statements	Quarterly within 45 days		Yes	No	N/A
2)	Annual (CPA Audited) statements	Within 90 days after FYE		Yes	No	N/A
3)	Annual Financial Projections/Budget (prepared on a quarterly basis)	Annually (within 30 days of FYE), and when revised		Yes	No	N/A
4)	8-K, 10-K and 10-Q Filings	If applicable, within 5 days of filing		Yes	No	N/A
5)	Compliance Certificate	Quarterly within 45 days		Yes	No	N/A
6)	Total amount of Borrower's cash and cash equivalents at the last day of the measurement period		\$	Yes	No	N/A
7)	Total amount of Borrower's Subsidiaries' cash and cash equivalents at the last day of the measurement period		\$	Yes	No	N/A

<u>Deposit and Securities Accounts</u> (Please list all accounts; attach separate sheet if additional space needed)

	Institution Name	Account Number	New Accoun	t?	Account Control Agreem	ent in place?
1)			Yes	No	Yes	No
2)			Yes	No	Yes	No
3)			Yes	No	Yes	No
4)			Yes	No	Yes	No

### **Other Matters**

1)	Have there been any changes in Key Persons since the last Compliance Certificate?	Yes	No
2)	Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement?	Yes	No
3)	Have there been any new or pending claims or causes of action against Borrower that involve more than Two Hundred Fifty Thousand Dollars (\$250,000.00)?	Yes	No
4)	Have there been any amendments of or other material changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate.	Yes	No

KEZAR LIFE SCIENCES, INC.		
ByName:Title:		
Date:		
	LENDER USE ONLY	
	Received by:	Date:
	Verified by:	Date:
	Compliance Status: Yes No	

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

Exceptions

### EXHIBIT D

### **Form of Secured Promissory Note**

[see attached]

# SECURED PROMISSORY NOTE (Term [A][B][C][D][E] Loan)

\$ Dated: [], 2021
FOR VALUE RECEIVED, the undersigned, KEZAR LIFE SCIENCES, INC., a Delaware corporation with offices located at 4000 Shoreline Court, Suite 300, South San Francisco, CA 94080 ("Borrower") HEREBY PROMISES TO PAY to the order of OXFORD FINANCE LLC ("Lender") the principal amount of [] MILLION DOLLARS (\$) or such lesser amount as shall equal the outstanding principal balance of the Term [A][B][C][D][E] Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term [A][B][C][D][E] Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated November 4, 2021 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the "Loan Agreement"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.
Principal, interest and all other amounts due with respect to the Term [A][B][C][D][E] Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this " <b>Note</b> "). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.
The Loan Agreement, among other things, (a) provides for the making of a secured Term [A][B][C][D][E] Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.
This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.
This Note and the obligation of Borrower to repay the unpaid principal amount of the Term [A][B][C][D][E] Loan, interest on the Term [A][B][C][D][E] Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.
Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.
Borrower shall pay all reasonable documented out-of-pocket fees and expenses, including, without limitation, reasonable documented out-of-pocket attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.
This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of California.
The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.
[Balance of Page Intentionally Left Blank]

By Name: Title:

IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

**BORROWER:** 

KEZAR LIFE SCIENCES, INC.

### LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL

	Principal		Scheduled	
Date	Amount	Interest Rate	Payment_Amount	Notation By

#### CORPORATE BORROWING CERTIFICATE

BORROWER: KEZAR LIFE SCIENCES, INC. DATE: November 4, 2021

LENDER: OXFORD FINANCE LLC, as Collateral Agent and Lender

I hereby certify as follows, as of the date set forth above:

- 1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.
- 2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.
- 3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.
- 4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

**R**ESOLVED, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

<u>Name</u>	<u>Title</u>	<u>Signature</u>	Authorized to Add or Remove <u>Signatories</u>

**R**ESOLVED FURTHER, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

RESOLVED FURTHER, that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from the Lenders.

**Execute Loan Documents**. Execute any loan documents any Lender requires.

**Grant Security**. Grant Collateral Agent a security interest in any of Borrower's assets.

**Negotiate Items**. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.

**Further Acts.** Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

RESOLVED FURTHER, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

[Balance of Page Intentionally Left Blank]

5.	5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.				
	By:				
	Name:				
	Title:				
aut I, tl	*** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.  I, the of Borrower, hereby certify as to paragraphs 1 through 5 above, as [print title] of the date set forth above.				
	Ву:				
	Name:				
	Title:				
	[Signature Page to Corporate Borrowing Certificate	1			
,					

### **EXHIBIT A**

# Certificate of Incorporation (including amendments)

[see attached]

# **EXHIBIT B**

### **Bylaws**

[see attached]

DEBTOR: KEZAR LIFE SCIENCES, INC. SECURED PARTY: OXFORD FINANCE LLC, as Collateral Agent

#### EXHIBIT A TO UCC FINANCING STATEMENT

#### **Description of Collateral**

The Collateral consists of all of Debtor's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below)], commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessories, accessories and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any Intellectual Property, including but not limited to, for the avoidance of doubt, any Intellectual Property licensed to Borrower pursuant to the terms of that certain Exclusive License Agreement, dated as of June 11, 2015, by and between Borrower and Onyx Therapeutics, Inc.; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property; provided further that if a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property solely to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that constitute proceeds of the Intellectual Property; and (ii) more than sixty-five percent (65%) of the total combined voting power of the issued and outstanding voting capital stock, membership units, or other securities owned or held of record by Borrower or its Subsidiary in such Foreign Subsidiary, if Borrower demonstrates to the reasonable satisfaction of Collateral Agent that such Foreign Subsidiary does not satisfy the holding period requirement pursuant to Section 245A of the IRC; (iii) any license, interest or contract, in each case if the granting of a Lien in such license, interest or contract is prohibited by or would constitute a default under the agreement governing such license, interest or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohi

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Debtor has agreed not to encumber any of its Intellectual Property.

Capitalized terms used but not defined herein have the meanings ascribed in the Uniform Commercial Code in effect in the State of California as in effect from time to time (the "Code") or, if not defined in the Code, then in the Loan and Security Agreement by and between Debtor, Secured Party and the other Lenders party thereto (as modified, amended and/or restated from time to time).

#### **Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the registration statements (No. 333-225769, 333-230520, 333-237133 and 333-254161) on Form S-8 and the registration statement (No. 333-261774) on Form S-3 of our report dated March 17, 2022, with respect to the consolidated financial statements of Kezar Life Sciences, Inc. and subsidiary.

/s/ KPMG LLP

San Francisco, California March 17, 2022

# 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 Annual Report on 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(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 17, 2022

By: /s/ John Fowler

John Fowler

Chief Executive Officer (Principal Executive Officer)

# 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 Annual Report on 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(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 17, 2022

By: /s/ Marc Belsky

Marc Belsky

Marc Belsky Chief Financial Officer (Principal Financial Officer)

# 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, 2021, 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.

/s/ John Fowler /s/ Marc Belsky

John Fowler Chief Executive Officer (Principal Executive Officer)

Date: March 17, 2022

Marc Belsky Chief Financial Officer (Principal Financial Officer)