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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

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

Commission File Number 001-38542

Kezar Life Sciences, Inc.
(Exact name of Registrant as specified in its charter)

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

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

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

Title of each 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 12(g) of the Act: **None**

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

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

The aggregate market value of the 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, 2020, was approximately $174 million.

The number of shares of Registrant's Common Stock outstanding as of March 8, 2021 was 48,066,343.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the 2021 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, 2020.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- statements regarding the impact of the 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.

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:

- The COVID-19 pandemic may cause disruptions to our business and negatively affect our ability to enroll and conduct our clinical trials.
- 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 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. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.
- 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.
- We may encounter substantial delays or difficulties in enrolling and retaining patients in our clinical trials.
- Clinical trials are very expensive, time consuming and difficult to design and implement.
- 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.
- 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.
- 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.
- 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.
- If the market opportunities for KZR-616 or KZR-261 are smaller than we believe they are, our business may suffer.
- We face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.
- 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.
- 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, support and monitor our preclinical studies and clinical trials. If those third parties perform in an unsatisfactory manner, it may harm our business.
- If we are unable to obtain and maintain patent protection for KZR-616 and KZR-261, or 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.
- 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.
- 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.

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 now leveraging its broad therapeutic potential in two Phase 2 clinical trials, MISSION and PRESIDIO, treating patients with severe autoimmune diseases characterized by high levels of unmet 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, PM, indications for which we 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 intend to identify additional immune-mediated disease indications of high disease morbidity and/or mortality and with prevalence in the range of 10,000 to 200,000 patients in the United States where a proof of principle exists to further develop 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. The compelling published activity seen with non-selective proteasome inhibitors administered to patients with severe autoimmune diseases provides proof of principle that inhibiting the immunoproteasome results in broad immunomodulatory benefit. Based on results from our Phase 1a studies in healthy volunteers and the preliminary results from the Phase 1b portion of our MISSION clinical trial in patients with systemic lupus erythematosus, or SLE, KZR-616 has largely avoided the adverse effects associated with currently marketed non-selective proteasome inhibitors, as exhibited in clinical studies conducted by third parties, including side effects which we believe prevent them from being utilized as a chronic treatment in autoimmune disorders. We have seen encouraging clinical activity and biomarker data in the SLE and LN patients who received KZR-616 in the Phase 1b portion of the MISSION trial.

Additionally, we are advancing our novel research platform targeting the Sec61 translocon and the protein secretion pathway to discover and develop small molecule therapeutics for oncology and autoimmune indications. Our first clinical candidate in this program, KZR-261, has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies. We anticipate submitting an investigational new drug, or IND, application for KZR-261 to the FDA in mid-2021 and initiating a Phase 1 clinical trial in solid tumors shortly thereafter. The clinical and nonclinical sections of the IND package are complete, and we are in the process of completing the final portions regarding manufacturing and stability. We believe this discovery platform has the potential to yield additional small molecule product candidates that offer the potential of combination therapy in a single agent. 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

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

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 immune-mediated diseases. In addition, we believe that KZR-616, if successfully developed and approved, may have the ability to become the standard of care across a range of immune-mediated diseases based on the following key attributes:

- broad immunomodulatory activity that may allow it to outperform approved therapies and to work in indications where other drugs have failed;
- subcutaneous, once weekly dosing schedule which is also amenable to patient self-administration;
- rapid drug clearance from the plasma with a half-life of less than two hours;
- full recovery of immunoproteasome activity occurs within three to seven days; and
- avoidance of systemic toxicities and peripheral neuropathy associated with dual proteasome inhibitors.

KZR-616 is the result of long-term research and development efforts led by our President, Co-Founder, and Chief Scientific Officer, Christopher Kirk PhD, which originated at Onyx Therapeutics, Inc., or Onyx. We acquired exclusive worldwide rights to KZR-616 and an accompanying library of similar molecules pursuant to a license agreement with 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.

Immune-mediated Diseases and Selective Inhibition of the Immunoproteasome

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 (a type of immune cell), 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 via 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.

Proof of Principle

Dual-targeting proteasome inhibitors, such as Velcade® (bortezomib), Kyprolis® (carfilzomib) and Ninlaro® (ixazomib), which are approved for the treatment of multiple myeloma, potently inhibit both the constitutive proteasome and immunoproteasome. This dual-targeting profile is necessary to make them effective treatments for multiple myeloma, and these malignant cells happen to express both forms of proteasome to handle their high levels of protein turnover. However, dual proteasome inhibition is associated with hematologic issues such as thrombocytopenia, neutropenia and anemia, as well as constitutional toxicities such as fatigue and myalgia. In addition, Velcade and Ninlaro are associated with risk of peripheral neuropathy, likely due to the off-target activity of these drugs against proteins found in peripheral neurons.

Despite this, Velcade has been used off-label in patients with severe and/or refractory autoimmune disease and demonstrated clinical activity in several autoimmune diseases, including lupus, lupus nephritis, rheumatoid arthritis, immune thrombocytopenia, autoimmune hemolytic anemia, primary Sjögren’s syndrome and graft-versus-host disease. In preclinical models, proteasome inhibition with Velcade and selective immunoproteasome inhibition with KZR-616 or ONX-0914 blocked production of most inflammatory cytokines, including many of those targeted by current biologic drugs. However, long-term, chronic administration of Velcade in the setting of autoimmune diseases is not considered feasible due to its side effect profile, in particular hematologic toxicities and risk of peripheral neuropathy. As a result, we believe that selectively targeting the immunoproteasome remains an untapped and promising approach for the chronic treatment of autoimmune diseases.

Clinical Development of KZR-616

We are focusing our initial development of KZR-616 in severe, chronic and orphan immune-mediated diseases where limited treatment options exist.

Phase 2 Clinical Trials

PRESIDIO is a Phase 2 randomized, placebo-controlled, double-blind, crossover, multicenter trial to evaluate the safety, tolerability, efficacy, pharmacokinetics, or PK, and pharmacodynamics, or PD, 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). We expect to enroll 24 patients in the trial. Patients completing the study then have the opportunity to enroll into an open-label extension study to continue receiving KZR-616 treatment for 12 months. Top-line data from PRESIDIO are expected in the first half 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.

The Phase 2 portion of MISSION is an open-label trial to demonstrate the responder rate of KZR-616 in patients with active lupus nephritis. During the 6-month treatment period patients receive 60 mg of KZR-616 subcutaneously once weekly (first dose of 30 mg) in addition to standard background therapy. The primary efficacy endpoint of the trial is the proportion of patients achieving greater than 50% reduction in urine protein to creatinine ratio, or UPCR, at six months. Secondary endpoints include safety and tolerability, additional renal response parameters (for example, complete renal response); extra-renal SLE disease indices; and change in biomarkers. Interim data are expected in late 2021, and top-line data are expected in the first half of 2022.

Phase 1 Clinical Trials

We have conducted two Phase 1a clinical trials with KZR-616 in healthy volunteers with 100 patients receiving KZR-616. Additionally, the Phase 1b portion of our MISSION clinical trial in SLE patients, with and without nephritis, has enrolled 47 patients at various dosing levels. The Phase 1b portion of the MISSION trial has been completed, and we expect to present final results in mid-2021. The initial results from these studies have been presented at numerous medical conferences and support the development of KZR-616 with doses of up to 75mg in immune-mediated diseases based on the following observations:

Safety and Tolerability

- KZR-616 appears to be well-tolerated for up to 13 weeks of treatment.
- The safety profile does not indicate the need for patient monitoring.

Activity and Biomarkers

- Improvement was exhibited across all measures of disease activity.
- Reduction in key biomarkers of disease activity.
    - Two of two patients with active lupus nephritis in our Phase 1a MISSION study experienced greater than 50% reduction in UPCR.
    - Seven of seven patients with elevated anti-dsDNA levels at baseline experienced reductions after treatment with KZR-616.
- Rapid and sustained anti-inflammatory gene expression changes.

Pharmacokinetics and Pharmacodynamics

- Consistent PK and PD across patients with repeat dosing.
- Target levels of immunoproteasome inhibition at doses at and above 30 mg of KZR-616.

Initial Indications for KZR-616

Due to its broad immunomodulatory profile, we believe that KZR-616 has the potential to address multiple chronic-immune mediated diseases. We are currently focusing our development efforts on immune-mediated diseases of high unmet need with prevalence in the range of 10,000 to 200,000 patients in the United States. We intend to identify additional indications to develop KZR-616.

Dermatomyositis and Polymyositis

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.

Lupus Nephritis

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 two recently FDA-approved drugs for the treatment of lupus nephritis. However, an unmet need still exists for treatments that can reduce disease activity quickly and without widespread immunosuppression.

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

KZR-261 is a novel first-in-class protein secretion inhibitor and our first clinical candidate nominated from our proprietary protein secretion platform. We expect to file an IND application for KZR-261 for the treatment of solid tumors in mid-2021. 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 to inhibit tumor growth in vivo in multiple models, including tumors resistant to traditional chemotherapeutics. The preclinical data generated with KZR-261 increases our confidence that inhibiting the Sec61 translocon could be effective against a variety of solid and hematologic tumor types.

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, immune-oncology and autoimmune indications.

We believe that protein secretion inhibitors targeting the Sec61 translocon have the potential to replicate the activity of biologic therapies, induce multi-target inhibition, and be designed for oral bioavailability. We have a 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. A plethora of 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, including orphan diseases and other areas of unmet needs.*** We believe that KZR-616 has the potential to treat a wide range of immune-mediated 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.

- ***Initiate the Phase 1 clinical trial of KZR-261 and expand our pipeline of small molecule disruptors of the protein secretion pathway.*** We believe KZR-261 has the potential to be a first-in-class therapeutic modulating the protein secretion pathway and the Sec61 translocon. We intend to continue leveraging this platform to identify additional product candidates for the treatment of diseases with significant clinical need, initially in oncology and immuno-oncology.

- ***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 current trials, KZR-616 is reconstituted in the hospital pharmacy prior to patient administration. 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. Merck KgaA has recently disclosed an LMP7-selective inhibitor that is currently being studied in a Phase 1 clinical trial in Multiple Myeloma.

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 Lukynis ™ (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 anifrolumab from AstraZeneca, and against IL-23/IL-12, such as Stelara from Janssen Biotech, Inc., and small molecule agents targeting JAK, such as baricitinib from Eli Lilly and Co., cereblon from Celgene, and BTK, such as evobrutinib, under evaluation by Merck KgaA.

In active, proliferative lupus nephritis, other companies are developing novel agents to add to the standard induction regimens, such as anifrolumab, the B-cell depleting agent obinutuzimab (Gazyva®) 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 14 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 2034. 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-616 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 Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

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

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

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

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

Federal false claims laws, including the federal civil False Claims Act, 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 a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

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

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors),and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

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

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

Coverage and Reimbursement

The future commercial success of our product candidates or any of our collaborators' ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for our product candidates. Government health administration authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government, through the Medicare or Medicaid programs, provides reimbursement for such treatments. In the United States, the European Union, or EU, and other potentially significant markets for our product candidates, government authorities and third party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the EU will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general.

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

Impact of Healthcare Reform on our Business

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

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

The PPACA became law in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers. Among other measures that may have an impact on our business, the PPACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Additionally, the PPACA extends manufacturers' Medicaid rebate liability, expanded eligibility criteria for Medicaid programs, and expands entities eligible for discounts under the Public Health Service pharmaceutical pricing program. 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 tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” 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 December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the Supreme Court has not yet ruled on the constitutionality of the PPACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 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 unclear how the Supreme Court ruling, other such litigation, 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 2030 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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, effective November 30, 2020, implementing a portion of the importation executive order providing guidance 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 pending review by the Biden administration until March 22, 2021. 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. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy 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, particularly in light of the new presidential administration. 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 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.

Employees and Human Capital Resources

As of December 31, 2020, we had 47 full-time employees, 36 of whom were primarily engaged in research and development activities and 12 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 COVID-19 pandemic and its potential impact on our business and the global economy.

Risks Related to the COVID-19 Pandemic

The COVID-19 pandemic may cause disruptions to our business.

The ongoing COVID-19 pandemic has led to the implementation of social distancing and public health safety measures, as well as adverse impacts on healthcare facilities and hospitals across the United States and in other countries where we conduct our clinical trials. The cumulative effect of restrictions related to COVID-19 may continue to disrupt our business, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations, as well as the duration of the COVID-19 pandemic. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Public health safety measures implemented as a result of COVID-19 may adversely impact our business operations, as well as the contract research organizations that support our clinical trials and third-party manufacturing facilities. Should any of these vendors experience disruptions, such as temporary closures or suspension of services, we would likely experience delays in advancing our preclinical studies and clinical trials as a result. Currently, however, we do not expect a material impact on the clinical supply of our product candidates.

The spread of COVID-19 has caused a broad impact globally and may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. The global pandemic of COVID-19 continues to rapidly evolve. The extent to which it impacts our business, our 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 closures 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.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

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

Our clinical trials will be affected by the COVID-19 pandemic. As a result of the demands on our healthcare system relating to COVID-19, we anticipate delays in our clinical development timelines and data release milestones for our product candidates. Clinical site initiation and patient enrollment will be delayed due to prioritizing hospital resources for the treatment of patients with COVID-19. The patients in our clinical trials may not be able to comply with clinical trial protocols if governmental orders or other safety measures impede travel and mobility or interrupt healthcare services. As a result, we may face delays in meeting our anticipated timelines for our ongoing and planned clinical trials. 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 imposed or recommended by federal or state governments, employers and others;
- 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 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 the coronavirus, 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.

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 $41.7 million, $35.1 million and $23.2 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $126.0 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;
- 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 studies and clinical trials of KZR-616 and KZR-261, as well as research and discovery activities 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 other regulatory authorities require us to perform clinical and other studies in addition to those that we currently anticipate. In addition, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to sales, marketing, manufacturing and distribution.

As of December 31, 2020, we had cash, cash equivalents and marketable securities of $140.4 million. We believe that our cash, cash equivalents and marketable securities as of December 31, 2020 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 or any future product candidates. Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize KZR-616 and any future product candidates.

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

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. In September 2020, we filed a shelf registration statement on Form S-3 (Registration No. 333-248752) that allows us to sell up to an aggregate of $200 million of our securities, which includes up to $50.0 million designated in a prospectus supplement for an at-the-market offering program, or the ATM program. We have sold an aggregate of approximately $11.0 million worth of our common stock pursuant to the ATM program, all of which occurred in February 2021, and approximately $189 million remains available under the 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. If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

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

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

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.

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 ending 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 ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs generated 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 the Tax Act.

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 pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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.

New tax laws or regulations could be enacted at any time, and existing tax laws or regulations could be interpreted, modified or applied in a manner that is adverse to us, which could adversely affect our business and financial condition. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or Tax Act, enacted many significant changes to the U.S. tax laws, including changes in corporate tax rates, the utilization of our NOLs and other deferred tax assets, the deductibility of expenses, and the taxation of foreign earnings. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, or any newly enacted federal tax legislation. The impact of changes under the Tax Act, the CARES Act, or future reform legislation could increase our future U.S. tax expense and could have a material adverse impact on our business and financial condition.

Risks Related to the Development and Commercialization of Our Product Candidates

Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of KZR-616, 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 agency.

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 other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program. In addition, the FDA typically refers applications for novel drugs to an advisory committee comprising outside experts. The FDA is not bound by the recommendation of the advisory committee, but it considers such recommendation when making its decision.

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

We have invested a significant portion of our time and limited financial and management resources in the development of KZR-616 and our protein secretion platform. 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 autoimmune indications and oncology. We are conducting research and discovery efforts targeting the protein secretion pathway and recently nominated KZR-261 as 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.

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 efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through earlier clinical trials.

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

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

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

Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. For example, as a result of the current demands on our healthcare system relating to the COVID-19 pandemic, we anticipated delays in our previously anticipated clinical development timelines and data release milestones for KZR-616. Moreover, circumstances may arise that could result in suspending or terminating our ongoing clinical trials. 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 other 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;
- 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 other 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, war, terrorism, natural disasters or public health epidemics.

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. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring competing drugs to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

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

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

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

Further, we, the FDA, other comparable regulatory authorities, or an IRB may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including cGCP, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our investigational new drug, or IND, 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.

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

Our product candidates will require clinical testing before we are prepared to submit an NDA for regulatory approval. We 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. The clinical trial process is also time consuming. Furthermore, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials.

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 autoimmune 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.

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 (CDER) at the FDA based on its primary mode of action as a drug, the FDA could disagree.

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 autoimmune 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 KZR-616 and any future product candidates. For KZR-261, we expect to file an IND application 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 COVID-19 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 contract research organizations, or CROs, and clinical trial 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 our ability to compel their actual performance.

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

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

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.

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.

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

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

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

The development and commercialization of new drugs is highly competitive. We face competition 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.

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.

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 other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of 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 other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell 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.

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 and any future product candidates in the European Union from the European Commission following the opinion of the European Medicines Agency, if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a product candidate is approved, the FDA or the European Commission, as the case may be, may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of KZR-616 and any future product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for our product candidates may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of 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.

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

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

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

If we seek approval of our product candidates outside of the United States, we expect that we will be subject to additional risks in commercialization including:

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

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 a scheme 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, 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),and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members, which will be expanded beginning in 2022, to require

applicable manufacturers to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist certified registered nurse anesthetists and certified nurse midwives during the previous year; 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.

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 or any future product candidates that we develop.

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

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

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

There have been executive, judicial and Congressional challenges to certain provisions 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 Act included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." 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 close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, but it is unclear when a decision will be made. Although the Supreme Court has not yet ruled on the constitutionality of the PPACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 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 unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the PPACA and our business. We continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 unless additional Congressional action is taken. COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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. 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, effective November 30, 2020, implementing a portion of the importation executive order providing guidance 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 pending review by the Biden administration until March 22, 2021. 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. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy 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.

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 other 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-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 other comparable regulatory authorities;
- our inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for drug components;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- our third-party manufacturers may not devote sufficient resources to our product candidates;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

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

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 Conference on 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

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

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

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

Given the amount of time required for the development, testing and regulatory review of new product candidates such as KZR-616 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.

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.

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.

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 and/or treatment in humans of cancerous or pre-cancerous diseases and/or conditions, including those related to hematological diseases and/or conditions.

The licensed compounds, including KZR-616, are selective for the immunoproteasome and therefore are not known or believed (based on scientific literature and the Company's own research and development activities) to have any application in cancer or pre-cancerous conditions. However, notwithstanding these known characteristics of the licensed compounds, Onyx retains all rights under the licensed intellectual property rights that are not granted to the Company, and therefore Onyx retains rights under such intellectual property rights to develop and commercialize the licensed compounds in connection with the diagnosis and/or treatment in humans of cancerous or pre-cancerous diseases and/or conditions, including those related to hematological diseases and/or conditions, and also has the rights to transfer these rights to a third-party. If 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.

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.

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.

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.

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.

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

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

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

Recruiting and retaining other senior executives, qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. 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.

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

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks on our technology environment. In addition, due to the COVID-19 pandemic, we have enabled substantially all of our employees to work remotely, which may make us more vulnerable to cyberattacks. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our, our third-party vendors' and/or business partners' information technology systems or other similar data security incidents could adversely affect our business operations or result in the loss, misappropriation, or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, outbreak of regional or global pandemic diseases such as the ongoing COVID-19 outbreak, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

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

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. 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 one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or drugs that may be important to the development of our business.

Risks Related to Ownership of Our Common Stock 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
- 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.

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. The price for our shares could, for example, decline significantly in the event that a large number of shares of our common stock are sold 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.

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, 2020, 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 46% 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. 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 ⅔% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, 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 March 8, 2021, there were approximately 26 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

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

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from the IPO

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

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

Prior to the date of this Annual Report on Form 10-K, we used all of the net offering proceeds from the IPO, primarily to advance our product candidates through clinical trial programs and for working capital and general corporate purposes.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Selected Financial Data.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

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

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

Overview

We are a clinical-stage biotechnology company, discovering and developing novel small molecule therapeutics to treat unmet needs in autoimmunity and cancer. We are developing our lead product candidate, KZR-616, a first-in-class selective immunoproteasome inhibitor, in severe autoimmune diseases where limited treatment options exist. We are conducting Phase 2 clinical trials of KZR-616 in three autoimmune diseases of high unmet need: the MISSION trial in patients with lupus nephritis; and the PRESIDIO trial in patients with dermatomyositis or polymyositis. We believe that the immunoproteasome is a validated target for the treatment of a wide variety of autoimmune diseases given the compelling published activity seen with non-selective proteasome inhibitors administered to patients with severe autoimmune diseases. Based on results from our Phase 1a studies in healthy volunteers and the preliminary results from the Phase 1b portion of the MISSION trial in patients with systemic lupus erythematosus, also known as lupus or SLE, KZR-616 has largely avoided adverse effects associated with currently marketed non-selective proteasome inhibitors, as exhibited in clinical studies conducted by third parties, including side effects which we believe prevent them from being utilized as a chronic treatment in autoimmune disorders. In addition, we have seen encouraging clinical activity and biomarker data in SLE patients.

Additionally, we are advancing our novel research platform targeting the Sec61 translocon and the protein secretion pathway to discover and develop small molecule therapeutics targeting oncology indications. Our first clinical candidate in this program, KZR-261, has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies. KZR-261 is undergoing laboratory studies and manufacturing activities in support of an investigational new drug application, which we anticipate submitting to the U.S. Food and Drug Administration in mid-2021 for a Phase 1 clinical trial in solid tumors. We believe this discovery platform has the potential to yield small molecule candidates that, if successfully developed and approved, 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 our resources to performing research and development activities in support of our product development efforts, hiring personnel, raising capital to support and expand such activities and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily from the issuance and sale of convertible preferred stock and from public offerings of common stock and pre-funded warrants to purchase common stock as described below. 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 $41.7 million, $35.1 million and $23.2 million for the years ended December 31, 2020, 2019 and 2018, respectively, and we expect to continue to incur significant losses for the foreseeable future. As of December 31, 2020, we had an accumulated deficit of $126.0 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 Polices and Estimates

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

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

Accrued Research and Development Costs

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

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed, the number of patients enrolled and the rate of patient enrollment may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. For the periods presented, we have experienced no material differences between our accrued expenses and actual expenses.

Stock-Based Compensation

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

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

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

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

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

Recent Accounting Pronouncements

See Note 2 to our Consolidated Financial Statements “Summary of Significant Accounting Policies—Accounting Pronouncements Adopted in 2020” for more information. There are no new accounting pronouncements yet to be adopted that are expected to have a material impact on our financial statements.

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,		
	2020	2019	2018
(dollars in millions)		(unaudited)	
Research and development expenses by program:			
KZR-616	$ 18.9	$ 17.4	$ 12.7
Protein Secretion	12.1	10.0	5.5
Total research and development expenses	$ 31.0	$ 27.4	$ 18.2

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 costs, allocated facilities costs and expenses for outside professional services, including legal, human resource, information technology and audit services. Personnel costs 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.

Results of Operations

A discussion regarding our financial condition and results of operations for the year ended December 31, 2019 compared to the year ended December 31, 2018 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, 2019, filed with the SEC on March 12, 2020.

Comparison of the Years Ended December 31, 2020 and 2019

	Year Ended December 31,			$ Change	
(dollars in millions)	**2020**	**2019**	**2018**	**2020 vs 2019**	**2019 vs 2018**
Operating expenses:					
Research and development	$ 31.0	$ 27.4	$ 18.2	$ 3.6	$ 9.2
General and administrative	11.9	10.0	6.6	1.9	3.4
Total operating expenses	42.9	37.4	24.8	5.5	12.6
Loss from operations	(42.9)	(37.4)	(24.8)	(5.5)	(12.6)
Interest income	1.2	2.3	1.6	(1.1)	0.7
Net loss	$ (41.7)	$ (35.1)	$ (23.2)	$ (6.6)	$ (11.9)

Research and Development Expenses

Research and development expenses increased by $3.6 million in 2020 compared to 2019. The increase was primarily due to an increase of $1.1 million in clinical trial related costs for KZR-616, an increase of $0.8 million in preclinical expenses related to the protein secretion program, an increase of $1.7 million in personnel expenses due to an increase in headcount, an increase of $0.3 million in stock-based compensation and an increase of $0.2 million in facility-related expenses, offset by a decrease of $1.0 million in manufacturing expenses. In addition, the Australian Research and Development Tax Incentive credit earned for the year ended December 31, 2020 decreased by $0.5 million compared to the same period in 2019, which is recorded as a reduction in our research and development expenses.

General and Administrative Expenses

General and administrative expenses increased by $1.9 million in 2020 compared to 2019. The increase was primarily due to an increase of $0.5 million in personnel expenses due to an increase in headcount and salaries, an increase of $0.6 million in stock-based compensation, an increase of $0.6 million in consulting and professional fees and an increase of $0.2 million in directors and officers liability insurance.

Interest Income

Interest income decreased by $1.1 million in 2020 compared to 2019. The decrease was attributable to lower interest rates on our marketable securities.

Liquidity and Capital Resources

Overview

As of December 31, 2020, we had $21.2 million in cash and cash equivalents and $119.2 million of marketable securities invested in a U.S. Treasury money market fund, U.S. Treasury securities, commercial paper and corporate debt securities. As of December 31, 2020, our cash equivalents and marketable securities had an average maturity of approximately six 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 $41.7 million for the year ended December 31, 2020, and we had an accumulated deficit of $126.0 million as of December 31, 2020.

We believe that our cash, cash equivalents and marketable securities as of December 31, 2020 will be sufficient to meet our projected operating requirements through at least the next 12 months from the date these financial statements are issued. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Public Offerings

In February 2020, we completed an underwritten public offering of 18,965,385 shares of our common stock and, to certain investors in lieu thereof, pre-funded warrants to purchase 2,884,615 shares of our common stock at an exercise price of $0.001 per share. The public offering price of our 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 public offering were approximately $53.3 million, after deducting underwriting discounts and commissions and other offering expenses paid by us.

In June 2020, we completed an underwritten public offering of 7,590,909 shares of our common stock and, to certain investors in lieu thereof, pre-funded warrants to purchase 909,091 shares of our common stock at an exercise price of $0.001 per share. In July 2020, we issued an additional 427,707 shares of common stock, pursuant to the exercise by the underwriters of their option to purchase additional shares of common stock. The public offering price of our common stock was $5.50 per share and the public offering price of the pre-funded warrants was $5.499 per underlying share. The net proceeds from the public offering were approximately $45.9 million, after deducting underwriting discounts and commissions and other offering expenses paid by us.

At-the-Market Offering Program

In September 2020, we entered into a Sales Agreement, or the 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 $50.0 million. Any shares of common stock sold will be issued pursuant to our shelf registration statement on Form S-3 (File No. 333-248752). 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 ATM Agreement and also have provided Cowen with indemnification and contribution rights. We sold approximately $11.0 million of our common stock pursuant to the ATM Agreement in February 2021, and approximately $39.0 million of common stock remains available for future sale.

Funding Requirements

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

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

- the progress, timing, scope, results and costs of our clinical trials and preclinical studies for our product candidates, including the ability to enroll patients in a timely manner for our clinical trials;
- the costs of obtaining clinical and commercial supplies for KZR-616, 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.

If we need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. The COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, 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

The following summarizes our cash flows for the periods indicated:

	Year Ended December 31,		
	2020	2019	2018
(dollars in millions)			
Net cash used in operating activities	$ (36.9)	$ (29.9)	$ (20.8)
Net cash (used in) provided by investing activities	(56.5)	20.4	(83.9)
Net cash provided by financing activities	99.6	0.3	77.9
Effect of exchange rate changes on cash, cash equivalents and restricted cash	0.1	—	(0.1)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 6.3	$ (9.2)	$ (26.9)

Cash Flows from Operating Activities

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.

During the year ended December 31, 2019, cash used in operating activities was $29.9 million, which consisted of a net loss of $35.1 million, adjusted by a net change of $0.9 million in our net operating assets and liabilities and non-cash charges of $4.3 million. The non-cash charges consisted of $1.3 million for depreciation and amortization and $4.0 million for stock-based compensation expense, offset by $1.0 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 $0.5 million in prepaid expenses and other current assets and a decrease of $0.8 million in operating lease liabilities, offset by an increase of $2.2 million in accounts payable and accrued expenses due to timing of payments and increased clinical and manufacturing expenditures.

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

Cash Flows from Investing Activities

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.

During the year ended December 31, 2019, cash provided by investing activities was $20.4 million primarily relating to the maturities of marketable securities $123.3 million exceeding purchases of such marketable securities $102.3 million. Payments for the purchases of property and equipment was $0.6 million during the year ended December 31, 2019.

During the year ended December 31, 2018, cash used in investing activities was $83.9 million primarily consisted of $119.2 million in purchases of marketable securities offset by $36.5 million of maturities of such marketable securities. Payments for the purchases of property and equipment was $1.1 million during the year ended December 31, 2018.

Cash Flows from Financing Activities

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 offerings and $0.4 million from the issuance of common stock pursuant to our employee equity plans.

During the year ended December 31, 2019, cash provided by financing activities was $0.3 million, consisting of proceeds from the issuance of common stock pursuant to our employee equity plans.

During the year ended December 31, 2018, cash provided by financing activities was $77.9 million consisting of $77.7 million in net proceeds from our IPO and $0.2 million from the issuance of common stock pursuant to our employee equity plans.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of December 31, 2020 (in millions):

CONTRACTUAL OBLIGATIONS	TOTAL	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating leases (1)	$ 6.7	$ 1.5	$ 3.2	$ 2.0	$ —
Total obligations	$ 6.7	$ 1.5	$ 3.2	$ 2.0	$ —

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

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

The contractual obligations table does not include any potential contingent payments upon the achievement by us of clinical, regulatory and commercial events, as applicable, or royalty payments that we may be required to make under license agreements we have entered into or may enter into with various entities pursuant to which we have in-licensed certain intellectual property, including our 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.

Off-Balance Sheet Arrangements

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

JOBS Act Accounting Election

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

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

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. The market risk inherent in our financial instruments and in our financial position reflects the potential losses arising from adverse changes in interest rates and concentration of credit risk. We had cash, cash equivalents and marketable securities of $140.4 million as of December 31, 2020, which consisted of bank deposits, highly liquid U.S. Treasury money market funds, U.S. Treasury securities, 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, 2020, our cash equivalents and marketable securities had an average maturity of approximately six 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 $0.1 million of our cash balance was located in Australia as of December 31, 2020. 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, 2020. Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, 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, 2020 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, 2020.

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.

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 2021 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 2021 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 2021 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 2021 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 2021 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

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

(a)(2) Financial Statement Schedules

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

(a)(3) Exhibits

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

Item 16. Form 10-K Summary

None.

Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38542), filed with the Commission on June 26, 2018).
3.2	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38542), filed with the Commission on June 26, 2018).
4.1	Form of Common Stock Certificate of the Company (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-225194), filed with the Commission on June 8, 2018).
4.2	Amended and Restated Investors' Rights Agreement, by and among the Company and certain of its stockholders, dated June 26, 2017 (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
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 (incorporated herein by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
10.5+	2015 Equity Incentive Plan, as amended (incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
10.6+	Form of Stock Option Agreement under the 2015 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
10.7+	Form of Stock Option Agreement—Early Exercise under the 2015 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
10.8+	2018 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 4.12 to the Company's Registration Statement on Form S-8 (File No. 333-225769), filed with the Commission on June 21, 2018).
10.9+	Non-Employee Director Compensation Plan.
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†	Executive Employment Agreement between the Company and Vassiliki Economides, dated January 14, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-38542), filed with the Commission on May 7, 2020.
10.15†	Exclusive License Agreement by and between the Company and Onyx Therapeutics, Inc., dated June 11, 2015 (incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A (File No. 333-225194), filed with the Commission on June 8, 2018).
10.16	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).
10.17	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 26, 2019).
21.1	Subsidiaries of the Company (incorporated herein by reference to Exhibit 21.1 to the Company's Registration Statement on Form S-1 (File No. 333-225194), filed with the Commission on May 24, 2018).
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page to this report).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibit 101).

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* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

\+ Indicates a management contract or compensatory plan.

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

SIGNATURES

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

Kezar Life Sciences, Inc.
(Registrant)

March 11, 2021	By: /s/ John Fowler John Fowler Chief Executive Officer (Principal Executive Officer)
March 11, 2021	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 11, 2021
/s/ Marc Belsky **Marc Belsky**	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 11, 2021
/s/ John-Pierre Sommadossi, Ph.D. **John-Pierre Sommadossi, Ph.D.**	Chairman of the Board of Directors	March 11, 2021
/s/ Franklin Berger **Franklin Berger**	Director	March 11, 2021
/s/ Graham Cooper **Graham Cooper**	Director	March 11, 2021
/s/ Jason Dinges, Ph.D. **Jason Dinges, Ph.D.**	Director	March 11, 2021
/s/ Elizabeth Garner, M.D. **Elizabeth Garner, M.D.**	Director	March 11, 2021
/s/ Michael Kauffman, M.D., Ph.D. **Michael Kauffman, M.D., Ph.D.**	Director	March 11, 2021
/s/ Christopher Kirk, Ph.D. **Christopher Kirk, Ph.D.**	President, Chief Scientific Officer and Director	March 11, 2021

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Kezar Life Sciences, Inc. and subsidiary (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for leases as of January 1, 2019 due to the adoption of FASB Accounting Standards Update 2016-02, *Leases (Topic 842)*.

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 11, 2021

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 21,228	$ 14,951
Marketable securities	119,219	63,255
Prepaid expenses	2,733	1,878
Other current assets	1,631	1,048
Total current assets	144,811	81,132
Property and equipment, net	3,435	4,282
Operating lease right-of-use asset	3,314	3,817
Other assets	282	282
Total assets	$ 151,842	$ 89,513
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,358	$ 823
Accrued liabilities	3,021	4,218
Operating lease liabilities, current	1,042	900
Other liabilities, current	21	62
Total current liabilities	6,442	6,003
Operating lease liabilities, noncurrent	4,422	5,464
Total liabilities	10,864	11,467
Stockholders' equity:		
Common stock, $0.001 par value, 125,000,000 shares authorized as of December 31, 2020 and 2019; 46,359,743 and 19,208,077 shares issued and outstanding as of December 31, 2020 and 2019, respectively	46	19
Preferred stock, $0.001 par value, 10,000,000 shares authorized, zero shares issued and outstanding as of December 31, 2020 and 2019	—	—
Additional paid-in capital	267,093	162,505
Accumulated other comprehensive loss	(137)	(196)
Accumulated deficit	(126,024)	(84,282)
Total stockholders' equity	140,978	78,046
Total liabilities and stockholders' equity	$ 151,842	$ 89,513

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

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

	Year Ended December 31, 2020	2019	2018
Operating expenses:			
Research and development	$ 30,981	$ 27,363	$ 18,136
General and administrative	11,969	9,979	6,590
Total operating expenses	42,950	37,342	24,726
Loss from operations	(42,950)	(37,342)	(24,726)
Interest income	1,208	2,255	1,559
Net loss	$ (41,742)	$ (35,087)	$ (23,167)
Net loss per common share, basic and diluted	$ (0.95)	$ (1.84)	$ (2.26)
Weighted-average shares used to compute net loss per common share, basic and diluted	44,004,190	19,083,826	10,264,584

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

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

	Year Ended December 31,		
	2020	2019	2018
Net loss	$ (41,742)	$ (35,087)	$ (23,167)
Other comprehensive income (loss), net of tax:			
Foreign currency translation adjustments	82	(45)	(72)
Unrealized (loss) gain on marketable securities	(23)	52	(20)
Total other comprehensive income (loss), net of tax	59	7	(92)
Comprehensive loss	$ (41,683)	$ (35,080)	$ (23,259)

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

KEZAR LIFE SCIENCES, INC.

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

(In thousands, except share and per share amounts)

	REDEEMABLE CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED OTHER COMPREHENSIVE	ACCUMULATED	TOTAL STOCKHOLDERS'
	SHARES	AMOUNTS	SHARES	AMOUNTS	CAPITAL	INCOME (LOSS)	DEFICIT	EQUITY (DEFICIT)
Balance at December 31, 2017	12,263,126	$ 77,931	948,578	$ 1	$ 451	$ (111)	$ (26,028)	$ (25,687)
Conversion of redeemable convertible preferred stock to common stock	(12,263,126)	(77,931)	12,263,126	12	77,919	—	—	77,931
Issuance of common stock upon initial public offering, net of issuance costs	—	—	5,750,000	6	77,689	—	—	77,695
Issuance of common stock under employee stock incentive plans, net of amount related to early exercised options	—	—	142,528	—	55	—	—	55
Issuance of common stock upon vesting of restricted stock units	—	—	10,189	—	—	—	—	—
Vesting related to shares of common stock issued pursuant to early exercises	—	—	—	—	69	—	—	69
Stock-based compensation expense	—	—	—	—	1,993	—	—	1,993
Other comprehensive loss	—	—	—	—	—	(92)	—	(92)
Net loss	—	—	—	—	—	—	(23,167)	(23,167)
Balance at December 31, 2018	—	—	19,114,421	19	158,176	(203)	(49,195)	108,797
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

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

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

	Year Ended December 31, 2020	2019	2018
Cash flows from operating activities:			
Net loss	$ (41,742)	$ (35,087)	$ (23,167)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,544	1,301	690
Stock-based compensation	4,943	4,007	1,993
Amortization of premiums and discounts on marketable securities	317	(979)	(476)
Loss on disposal of property and equipment	—	—	106
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	(1,424)	(553)	(1,136)
Other assets	—	—	61
Accounts payable and accrued liabilities	313	2,208	1,440
Operating lease liabilities and other liabilities	(900)	(774)	(8)
Deferred rent	—	—	(295)
Net cash used in operating activities	(36,949)	(29,877)	(20,792)
Cash flows from investing activities:			
Purchases of property and equipment	(194)	(607)	(1,120)
Purchases of marketable securities	(225,728)	(102,255)	(119,244)
Maturities of marketable securities	169,424	123,281	36,450
Proceeds from sale of property and equipment	—	—	10
Net cash provided by (used in) investing activities	(56,498)	20,419	(83,904)
Cash flows from financing activities:			
Proceeds from sale of common stock and pre-funded warrants in underwritten offerings, net of offering costs	99,186	—	77,695
Proceeds from issuance of common stock under employee stock incentive plans	456	272	218
Net cash provided by financing activities	99,642	272	77,913
Effect of exchange rate changes on cash, cash equivalents and restricted cash	82	(45)	(81)
Net (decrease) increase in cash, cash equivalents and restricted cash	6,277	(9,231)	(26,864)
Cash, cash equivalents and restricted cash at the beginning of period	14,951	24,182	51,046
Cash, cash equivalents and restricted cash at the end of period	$ 21,228	$ 14,951	$ 24,182
Supplemental disclosures of noncash investing and financing information:			
Reclassification of employee stock liability to equity upon vesting	$ 41	$ 50	$ 69
Addition of tenant improvement paid by landlord	$ —	$ —	$ 2,703
Purchase of property and equipment in accounts payable	$ —	$ —	$ 38
Conversion of redeemable convertible preferred stock into common stock	$ —	$ —	$ 77,931
Unpaid offering costs in accrued liabilities	$ 25	$ —	$ —

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

1. Organization and Description of the Business

Description of Business

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

Reverse Stock Split

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

Liquidity

Since commencing operations in mid-2015, substantially all of the Company's efforts have been focused on research, development, and the advancement of the Company's lead product candidate, KZR-616. The Company's ultimate success depends on the outcome of the ongoing research and development activities. The Company has not yet generated product sales and as a result has experienced operating losses since inception and had an accumulated deficit of $126.0 million as of December 31, 2020. 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, 2020 will be sufficient to fund the Company's cash requirements for at least 12 months following the issuance of these financial statements.

In September 2020, the Company entered into a Sales Agreement (the "ATM Agreement") with Cowen and Company, LLC ("Cowen"), pursuant to which the Company can offer and sell, from time to time at its sole discretion through Cowen, as its sales agent, shares of common stock having an aggregate offering price of up to $50.0 million. Any shares of common stock sold will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-248752). The Company 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 ATM Agreement and also has provided Cowen with indemnification and contribution rights. The Company has sold an aggregate of approximately $11 million worth of its common stock pursuant to the ATM Agreement, all of which occurred in February 2021.

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 our 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, an affiliate of Morningside Venture Investments Ltd, 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 our 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, together with its affiliate, Equal Talent Investments Limited, and certain of the Company's officers and directors purchased an aggregate of approximately $22.9 million of common stock in the February Offering.

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

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, useful lives of fixed assets, stock-based compensation, and accrued research and development costs. Management bases its estimates on historical experience and on various other market-specific relevant assumptions that management believes to be reasonable under the circumstances. Actual results may differ from those estimates.

We also anticipate that the COVID-19 pandemic will continue to have an impact on the clinical and preclinical development timelines for our 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

With the global spread of the ongoing COVID-19 pandemic beginning in the first quarter of 2020, we have implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on our business. The extent to which the COVID-19 pandemic impacts our business, our preclinical and clinical development and regulatory efforts, our corporate development objectives and the value of and market for our 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 our business, financial condition, results of operations and growth prospects.

In addition, we are subject to other challenges and risks specific to our business and our ability to execute on our 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 our product candidates; delays or problems in the supply of our 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 our intellectual property rights; and complying with applicable regulatory requirements. In addition, to the extent the ongoing COVID-19 pandemic adversely affects our 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.

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, 2020, the majority of the

Company’s cash, cash equivalents and marketable securities were held by financial institutions in the United States, while approximately $0.1 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, 2020, 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.

Leases

The Company adopted ASU 2016-02, Leases (Topic 842) on January 1, 2019 using the modified retrospective approach and utilizing the effective date as its date of initial application, for which prior periods are presented in accordance with the previous guidance in ASC 840, Leases.

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 elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. The Company separately accounts for lease and non-lease components for all of its leases.

Research and Development Costs

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

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

Research and Development Tax Incentive

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

The Company recognized $58,000, $635,000 and $5,000 as a reduction of research and development expenses for the years ended December 31, 2020, 2019 and 2018, respectively, in connection with the research and development tax incentive from the ATO. As of December 31, 2020 and 2019, the research and development tax credit receivable was $766,000 and $642,000, 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.

Accounting Pronouncements Adopted in 2020

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses (Topic 326)* as well as subsequent amendments to the initial guidance under ASU 2018-19, ASU 2019-04 and ASU 2019-05 (collectively Topic 326). Topic 326 requires the measurement and recognition of expected credit losses for financial assets. Under the new guidance, an entity will recognize as an allowance its estimate of expected credit losses. The Company adopted the new standard using the modified retrospective approach as of January 1, 2020 and the adoption did not have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements on fair value measurements. The amendment of ASU No. 2018-13 removes disclosure requirements from Topic 820 in the areas of: (1) the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; (2) the policy for timing of transfers between levels; and (3) the valuation processes for Level 3 fair value measurements. The Company adopted the new standard as of January 1, 2020 and the adoption did not have a material impact on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes: Simplifying the Accounting for Income Taxes*, which removes certain exceptions to the general principles found in ASC740, *Income Taxes.* As part of the simplification, along with other exceptions, it removes the exception to the incremental approach for intraperiod tax allocation in the event of a loss from continuing operations and income or a gain from other items. The Company early adopted ASU 2019-12 as of January 1, 2020 and the adoption did not have a material 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.

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, 2020 or 2019.

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, 2020			
Financial Assets:	Total	Level 1	Level 2	Level 3
Money market funds	$ 19,347	$ 19,347	$ —	$ —
U.S. Treasury securities	107,708	107,708	—	—
Commercial paper	1,000	—	1,000	—
Corporate debt securities	10,511	—	10,511	—
Total	$ 138,566	$ 127,055	$ 11,511	$ —

	December 31, 2019			
Financial Assets:	Total	Level 1	Level 2	Level 3
Money market funds	$ 14,731	$ 14,731	$ —	$ —
U.S. Treasury securities	5,285	5,285	—	—
Commercial paper	15,186	—	15,186	—
Corporate debt securities	17,171	—	17,171	—
U.S. agency bonds	25,613	—	25,613	—
Total	$ 77,986	$ 20,016	$ 57,970	$ —

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, 2020 and 2019 (in thousands):

Financial Assets:	December 31, 2020 Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
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

Financial Assets:	December 31, 2019 Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 14,731	$ —	$ —	$ 14,731
U.S. Treasury securities	5,285	1	(1)	5,285
Commercial paper	15,174	12	—	15,186
Corporate debt securities	17,168	3	—	17,171
U.S. agency bonds	25,597	16	—	25,613
Total	$ 77,955	$ 32	$ (1)	$ 77,986

The Company has not recognized an allowance for credit losses on any securities in an unrealized loss position as of December 31, 2020 and 2019.

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, 2020 and 2019 (in thousands):

	December 31, 2020 Less than 12 consecutive months		December 31, 2019 Less than 12 consecutive months	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. Treasury securities	$ 43,202	$ (5)	$ 4,535	$ (1)
Corporate debt securities	9,006	(1)	—	—
Total	$ 52,208	$ (6)	$ 4,535	$ —

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, 2020, the amortized cost and estimated fair value of the Company's available-for-sale securities by contractual maturity are shown below (in thousands):

	Amortized Cost	Estimated Fair Value
Available-for-sale securities maturing:		
In one year or less	$ 138,557	$ 138,566
Total available-for-sale securities	$ 138,557	$ 138,566

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, 2020. 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 consisted of the following as of December 31, 2020 and 2019 (in thousands):

	December 31, 2020	December 31, 2019
Leasehold improvements	$ 3,268	$ 3,268
Furniture, laboratory and office equipment	2,750	2,578
Computer equipment	159	253
Total property and equipment	6,177	6,099
Less accumulated depreciation and amortization	(2,742)	(1,817)
Property and equipment, net	$ 3,435	$ 4,282

Depreciation expense was $0.9 million for the year ended December 31, 2020, $0.9 million for the year ended December 31, 2019 and $0.7 million for the year ended December 31, 2018.

Accrued Liabilities

Accrued liabilities consisted of the following as of December 31, 2020 and 2019 (in thousands):

	December 31, 2020	December 31, 2019
Accrued preclinical and research costs	$ 461	$ 1,687
Accrued clinical costs	929	1,027
Accrued employee-related costs	1,355	1,293
Accrued professional services	103	53
Other	173	158
Total accrued liabilities	$ 3,021	$ 4,218

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, we 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 our 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, 2020, the weighted average remaining lease term was 4.17 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, 2020	2019
Cash paid for operating lease liabilities	$ 900	$ 774
Operating lease costs	1,099	1,099
Variable lease costs	542	505

Maturities of lease liabilities as of December 31, 2020 were as follows for the years ending December 31:	
2021	$ 1,542
2022	1,588
2023	1,635
2024	1,684
2025	282
Total undiscounted lease payments	6,731
Less: imputed interest	(1,267)
Total lease liabilities	$ 5,464
Operating lease liabilities, current	1,042
Operating lease liabilities, noncurrent	4,422
Total operating lease liabilities	$ 5,464

For the years ended December 31, 2020, 2019 and 2018, the Company recognized $1.1 million, $1.1 million and $1.0 million of rent expense, respectively. Variable lease costs were $0.5 million, $0.5 million and $0.4 million for the years ended December 31, 2020, 2019 and 2018, respectively.

7. Redeemable Convertible Preferred Stock

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

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 our common stock (together with its affiliates) or the combined voting power of our 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 us 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, 2020, 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, 2020.

Issue Date	Classification	Exercise Price	Expiration Date	Number of shares 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, 2020, options to purchase 2,689,068 shares of common stock were outstanding under the 2018 Plan and 1,286,960 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, 2020, options to purchase 1,800,054 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, 2020, 137,668 shares of common stock had been issued under the ESPP and 445,556 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, 2020.

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	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	3,107,066	$ 7.19	8.2	$ 3,151
Options granted	1,503,876	$ 3.87		
Options exercised	(56,653)	$ 1.95		$ 185
Options cancelled/forfeited	(65,167)	$ 7.84		
Outstanding at December 31, 2020	4,489,122	$ 6.14	7.8	$ 7,134
Vested and exercisable at December 31, 2020	2,358,197	$ 5.62	7.0	$ 4,627

The weighted average grant date fair value of options granted during the years ended December 31, 2020 and 2019 was $2.76 and $9.33 per share, respectively. The aggregate intrinsic value of exercised stock options during the years ended December 31, 2020 and 2019 was $185,000 and $292,000, 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 our board of directors.

As of December 31, 2020 and 2019, there were 8,859 and 30,027 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, 2020 and 2019, the Company recorded in other current liabilities $21,000 and $62,000, 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,		
	2020	2019	2018
Research and development	$ 2,102	$ 1,777	$ 842
General and administrative	2,841	2,230	1,151
Total stock-based compensation expense	$ 4,943	$ 4,007	$ 1,993

As of December 31, 2020, the unrecognized stock-based compensation cost was $9.6 million with an estimated weighted average amortization period of 2.4 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		
	Year Ended December 31,			Year Ended December 31,		
	2020	2019	2018	2020	2019	2018
Expected term (years)	5.5 - 6.0	5.8 - 5.9	5.5 - 6.1	0.5	0.5	0.5
Expected volatility	83.8 - 91.9%	78.7 - 83.7%	82.0 - 83.2%	101.7 - 114.3%	73.7 - 109.9%	74.3%
Risk-free interest rate	0.4 - 1.6%	1.5 - 2.6%	2.6 - 3.1%	0.1 - 0.2%	1.6 - 2.4%	2.5%
Expected dividend yield	—	—	—	—	—	—

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

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, 2020, 2019 and 2018, the Company recorded matching contributions of approximately $326,000, $249,000 and $167,000, respectively.

13. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2020, 2019 and 2018. 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,		
	2020	2019	2018
Domestic	$ (41,599)	$ (34,181)	$ (23,047)
Foreign	(143)	(906)	(120)
Total	$ (41,742)	$ (35,087)	$ (23,167)

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 $373,000, $284,000 and $175,000 of R&D tax credits as a reduction of payroll expenses to offset its payroll tax liabilities for the years ended December 31, 2020, 2019 and 2018, respectively.

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

	Year Ended December 31,		
	2020	2019	2018
Federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State taxes, net of federal benefit	1.1	0.9	6.4
Foreign tax rate differential	0.0	0.2	0.1
Permanent differences	(2.7)	(1.7)	0.3
Research and development credit	2.6	1.9	1.4
Change in valuation allowance	(22.0)	(22.3)	(29.2)
Provision for income taxes	— %	— %	— %

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

	Year Ended December 31, 2020	2019	2018
Deferred tax assets			
Reserves and accruals	$ 1,665	$ 1,056	$ 1,009
Net operating loss carryforwards	24,824	16,986	10,985
Research and development credit carryforwards	2,938	2,177	1,194
Lease Liabilities	1,148	1,336	—
Gross deferred tax assets	30,575	21,555	13,188
Valuation allowance	(29,410)	(20,196)	(12,560)
Net deferred tax assets	1,165	1,359	628
Deferred tax liabilities			
Property and equipment	(469)	(557)	(628)
Right-of-use asset	(696)	(802)	—
Net deferred tax	$ —	$ —	$ —

Realization of the deferred tax assets is dependent upon future taxable income. Since the amount and timing of future income are uncertain, the net deferred tax assets, as of December 31, 2020, and December 31, 2019 have been fully offset by a valuation allowance. The valuation allowance increased approximately $9.2 million, $7.6 million and $5.1 million during the years ended December 31, 2020, 2019, and 2018, respectively.

As of December 31, 2020, the Company had federal net operating loss ("NOL") carryforward of $109.7 million and a federal research and development tax credit carryforward of $2.4 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 $87.6 million generated from years ended after December 31, 2017, carryforward indefinitely. As of December 31, 2020 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 $1.8 million, which does not expire.

As of December 31, 2020, the Company also had accumulated Australian tax losses of $1.9 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, 2020. 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 $0.9 million of unrecognized tax benefits as of December 31, 2020. No liability related to uncertain tax positions is recorded on the financial statements. All uncertain tax positions are currently recorded as a reduction to our 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, 2020. A reconciliation of our unrecognized tax benefits for the year ended December 31, 2020 is as follows (in thousands):

	Unrecognized Income Tax Benefits
Balance as of December 31, 2019	$ —
Additions for prior year tax positions	381
Additions for current year tax positions	487
Balance as of December 31, 2020	$ 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,		
	2020	2019	2018
Numerator:			
Net loss	$ (41,742)	$ (35,087)	$ (23,167)
Denominator:			
Weighted-average shares of common stock outstanding	44,004,190	19,083,826	10,264,584
Net loss per share, basic and diluted	$ (0.95)	$ (1.84)	$ (2.26)

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

	Year Ended December 31,		
	2020	2019	2018
Options to purchase common stock	4,489,122	3,107,066	2,181,466
Common stock subject to future vesting	8,859	30,027	89,257
Total	4,497,981	3,137,093	2,270,723

15. Selected Quarterly Financial Information (Unaudited)

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

	Quarter Ended			
(in thousands, except per share amounts)	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020
	(Unaudited)			
Operating expenses	$ 10,478	$ 9,853	$ 11,551	$ 11,068
Net loss	$ (10,012)	$ (9,500)	$ (11,289)	$ (10,941)
Net loss per share, basic and diluted	$ (0.30)	$ (0.22)	$ (0.23)	$ (0.22)

(in thousands, except per share amounts)	Quarter Ended March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
	(Unaudited)			
Operating expenses	$ 8,309	$ 9,355	$ 9,681	$ 9,997
Net loss	$ (7,642)	$ (8,718)	$ (9,148)	$ (9,579)
Net loss per share, basic and diluted	$ (0.40)	$ (0.46)	$ (0.48)	$ (0.50)

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

Exhibit 10.9

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: $35,000
   b. Non-executive chairperson of the Board: $65,000 (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. Annual Committee Chair Service Retainer (inclusive of Committee Member Service Retainer):
   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 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. Initial Grant: 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. Annual Grant: On the first market trading day after each annual stockholders 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.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Kezar Life Sciences, Inc.:

We consent to the incorporation by reference in the registration statements (No. 333-225769, 333-230520 and 333-237133) on Form S-8 and the registration statement (No. 333-248752) on Form S-3 of Kezar Life Sciences, Inc. and subsidiary of our report dated March 11, 2021, with respect to the consolidated balance sheets of Kezar Life Sciences, Inc. and subsidiary as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2020, and the related notes, which report appears in the December 31, 2020 annual report on Form 10-K of Kezar Life Sciences, Inc. and subsidiary.

Our report refers to a change in the method of accounting for leases as of January 1, 2019 due to the adoption of FASB Accounting Standards Update 2016-02, *Leases (Topic 842)*.

/s/ KPMG LLP

San Francisco, California
March 11, 2021

Exhibit 31.1

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

I, 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 11, 2021

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

Exhibit 31.2

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

I, Marc Belsky, certify that:

1. I have reviewed this 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 11, 2021

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

Exhibit 32.1

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

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

(1) The Company’s Annual Report on Form 10-K for the year ended December 31, 2020, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Date: March 11, 2021

/s/ John Fowler	/s/ Marc Belsky
John Fowler	Marc Belsky
Chief Executive Officer	Chief Financial Officer
(Principal Executive Officer)	(Principal Financial Officer)