2023 Annual Report

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

OR

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

Commission File Number 001-38542

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. ☐

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

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

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

The aggregate market value of the 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, 2023, was approximately $173 million.

The number of shares of Registrant's Common Stock outstanding as of March 10, 2024 was 72,801,359.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the 2024 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, 2023.

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

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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," "should," "would," "potential," "project," "plan," "expect," "seek," "target" or similar expressions, or the negative or plural of these words or expressions. These forward-looking statements include statements concerning the following:

- our plans to develop and commercialize our product candidates;
- the initiation, timing, progress and 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 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;
- the potential milestone and royalty payments under certain of our license agreements;
- 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;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad, including as a result of bank failures, public health crises or geopolitical tensions;
- the impact of government laws and regulations;
- developments relating to our competitors and our industry; and
- other 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. The forward-looking statements in this report reflect our beliefs and opinions on the relevant subject based on information available to us as of the date of this Annual Report on Form 10-K. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements. Except as required by law, we are under no duty to update or revise any of the forward-looking statements in this report, whether as a result of new information, future events or otherwise, after the date of this report.

PART I

Item 1. Business.

Overview

We are a clinical-stage biotechnology company 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 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.

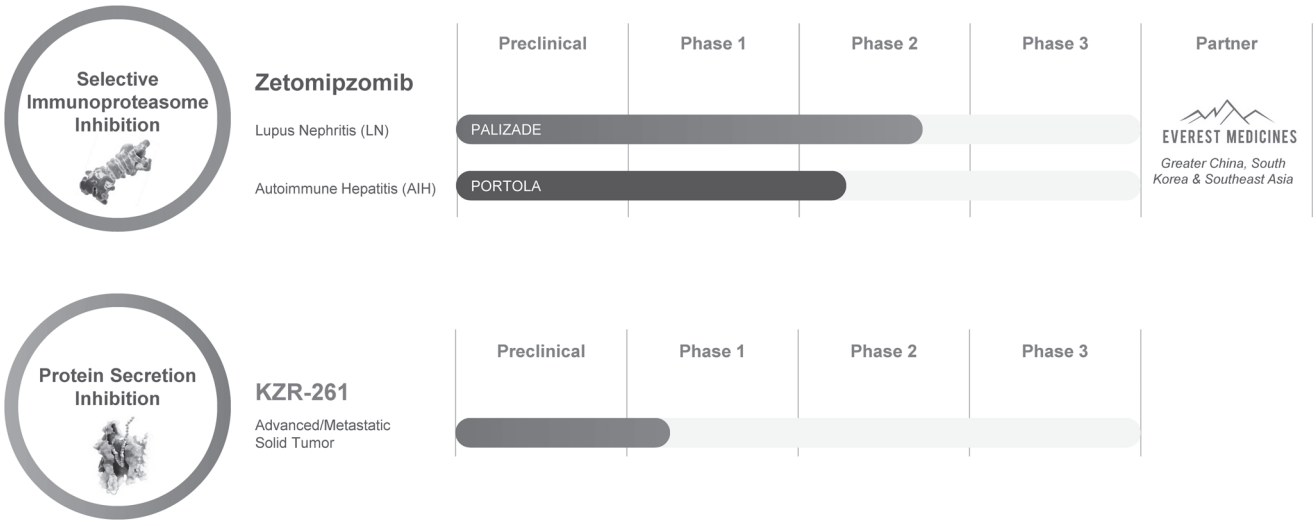
Our lead product candidate, zetomipzomib, is a first-in-class selective immunoproteasome inhibitor that has successfully completed Phase 1a testing in healthy volunteers and a Phase 1b/2a clinical trial in patients with systemic lupus erythematosus, or SLE, with or without lupus nephritis, or LN (the MISSION trial). We are now conducting PALIZADE, a global, placebo-controlled, double-blind Phase 2b clinical trial evaluating zetomipzomib in patients with LN. In addition, we are leveraging the broad therapeutic potential of zetomipzomib in other severe autoimmune diseases of high unmet medical need. Our PORTOLA trial is a placebo-controlled, double-blind Phase 2a clinical trial evaluating zetomipzomib in patients with autoimmune hepatitis, or AIH. We are also continuing to explore development opportunities for zetomipzomib in patients with SLE.

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

Our oncology product candidate, KZR-261, is a small molecule agent being studied in an open-label Phase 1 clinical trial designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, as well to explore preliminary anti-tumor activity. This study is being conducted in two parts: dose escalation in patients with locally advanced or metastatic solid malignancies, and dose expansion in patients with selected tumor types. KZR-261 was discovered from our novel research platform targeting the Sec61 translocon and the protein secretion pathway. KZR-261 has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies by targeting multiple pathways driving tumor growth and survival.

Our Pipeline

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



Zetomipzomib: Selective Immunoproteasome Inhibitor

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

- broad and potent immunomodulatory activity that may provide meaningful therapeutic benefit without immunosuppression across a range of treatable and currently untreatable immune-mediated diseases;
- subcutaneous, once weekly dosing schedule which is amenable to patient self-administration with the potential of less frequent dosing for chronic use;
- rapid drug clearance from the plasma with a half-life of less than five hours;
- minimal predicted clinically relevant risk for drug-drug interactions;
- no teratogenicity or reproductive toxicity observed in nonclinical studies;
- full recovery of immunoproteasome activity occurs within three to seven days following dose administration; and
- unique chemical structure leads to highly specific inhibition of the immunoproteasome without known off-target effects.

Clinical Development of Zetomipzomib

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

PALIZADE Phase 2b Trial

PALIZADE is a Phase 2b global, placebo-controlled, double-blind clinical trial evaluating the efficacy and safety of two dose-levels of zetomipzomib in patients with active LN. Target enrollment will be 279 patients, who will be randomly assigned (1:1:1) to receive 30 mg of zetomipzomib, 60 mg of zetomipzomib or placebo subcutaneously once weekly for 52 weeks, in addition to standard background therapy. Background therapy can, but will not be mandated to, include standard induction therapy. Over the initial 16 weeks, there will be a mandatory corticosteroid taper to 5 mg per day or less. End-of-treatment assessments will occur at Week 53, and the end-of-study assessments will occur at Week 57.

The primary efficacy endpoint is the proportion of patients who achieve a complete renal response, or CRR, at Week 37. CRR is defined as a urine protein-to-creatine ratio, or UPCR, of 0.5 or less and stable estimated glomerular filtration rate, or eGFR, in patients who have not received rescue or prohibited medications. Key secondary endpoints include: the proportion of patients achieving partial renal response, or PRR, at Weeks 25, 37 and 53 and the number of CRRs at Weeks 25 and 53. PRR is defined as a fifty percent or greater reduction in UPCR from baseline, as well as an absolute reduction of UPCR at or below 1.0, if the baseline is less than 3.0, or an absolute reduction of UPCR below 3.0, if the baseline is 3.0 or greater. The primary safety endpoint is the incidence and severity of adverse events. Additional secondary and exploratory endpoints include measures of SLE disease activity including flare. We expect a primary analysis from PALIZADE to occur in mid-2026, and we expect to receive the full end-of-treatment data in the second half of 2026.

LN is one of the most serious complications of SLE and is a disease comprising a spectrum of vascular, glomerular and tubulointerstitial lesions that 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 involving corticosteroids or similar immunosuppressive agents to prevent relapse. These therapies can increase the risks of infection and malignancy and cause a wide variety of side effects. There are FDA-approved drugs for the treatment of LN. However, an unmet need still exists for treatments that can reduce disease activity quickly and without widespread immunosuppression.

PORTOLA Phase 2a Trial

PORTOLA is a Phase 2a placebo-controlled, double-blind clinical trial evaluating the safety and efficacy of zetomipzomib in patients with AIH who are insufficiently responding to standard of care or have relapsed. Target enrollment will be 24 patients, who will be randomly assigned (2:1) to receive either zetomipzomib or placebo in addition to background corticosteroid therapy for 24 weeks and includes a protocol-mandated steroid taper by Week 14. The primary efficacy endpoint measures the proportion of patients who

achieve a complete response, measured as normalization of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels with a successful corticosteroid taper by Week 24. We expect to receive topline data from the PORTOLA trial by mid-2025.

AIH is a rare, chronic disease in which the immune system attacks the liver and causes inflammation and tissue damage, severely impacting patients' physical health and quality of life. Lifelong maintenance therapy is required to avoid relapse and burdensome adverse effects. If left untreated, AIH can lead to cirrhosis, liver failure and hepatocellular carcinoma. Standard of care treatment for AIH is chronic, immunosuppressive treatment with corticosteroids that do not address the pathophysiology of AIH, can result in significant toxicity associated with long-term use and often result in inadequate response or relapse after treatment withdrawal. There is a significant need for treatment regimens that reduce or remove the high dependency on chronic immunosuppression using corticosteroids.

Safety Profile

Safety and tolerability are monitored across clinical trials of zetomipzomib by study-specific data monitoring committees. To date, injection site reactions, or ISRs, are the most common treatment emergent adverse event. The ISRs occur at the time and site of injection, are described as redness, pain, itchiness or induration. The ISRs are not vasculitic or immunogenic. No clinically significant laboratory abnormalities have been noted; and specifically, we have not observed cytopenias, transaminase abnormalities or renal dysfunction. In addition, no opportunistic infections or serious infections have been observed to date. It was observed that upon initiation of zetomipzomib therapy, some patients experienced a constellation of symptoms that included low grade fever, headache, myalgias, nausea, and/or vomiting. Based on these observations, we introduced a dosing regimen where patients receive an initial dose of 30 mg of zetomipzomib followed by administration of the target dose of 45 mg, 60 mg or 75 mg of zetomipzomib. The introduction of an initial "step up" dose, together with prophylactic and supportive measures such as oral hydration with electrolyte-rich drinks, has substantially mitigated this early concern. Some patients have reported nausea and occasional vomiting on the day of dosing, which has also been mitigated with the use of optional oral hydration and/or oral or sublingual antiemetics. In longer term exposure to zetomipzomib during our PRESIDIO open-label extension trial, nine patients received zetomipzomib 45mg weekly for more than 12 months, including one patient who received zetomipzomib weekly for up to two years. With chronic exposure, no new safety or tolerability events were observed and there remained no signs or symptoms of immunosuppression.

Immune-Mediated Diseases and Selective Inhibition of the Immunoproteasome

We are focusing our development efforts on immune-mediated diseases of high unmet need and intend to identify additional indications to develop zetomipzomib. 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. These abnormal immune responses can lead to activation of inflammatory and cytotoxic T cells, which can cause further inflammation, activation of other inflammatory cells such as macrophages and results in tissue and organ damage.

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 with biologic agents or with powerful synthetic 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 agents. These therapies can increase the risks of infection and malignancy and cause 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.

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. Zetomipzomib is derived from medicinal chemistry efforts focused on potent and selective inhibition of the immunoproteasome-specific subunits LMP7 and LMP2.

In preclinical models of inflammation, selective inhibitors of the immunoproteasome were shown to block cytokine production and result in profound immunomodulatory therapeutic activity equivalent to or better than approved dual proteasome inhibitors without causing cytotoxicity. In over 15 peer-reviewed publications, our selective inhibitors of the immunoproteasome and related compounds have demonstrated strong therapeutic potential by blocking disease progressions in animal models multiple immune-mediated diseases. Additionally, this immunomodulatory response was broadly seen across many cell types of the immune system, including

both T-cells and B-cells, and was demonstrated in a non-immunosuppressive manner. This is distinct from other agents currently used to treat autoimmunity, which typically target a single cytokine or immune cell type or are broadly immunosuppressive.

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

KZR-261 is a novel, first-in-class protein secretion inhibitor and the first clinical candidate nominated from our protein secretion platform. KZR-261 acts through direct interaction and inhibition of Sec61translocon activity. The net effect is a single agent that works broadly to reduce oncogenic factors important to proliferation, metastasis and immune evasion in preclinical cancer models. 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. In multiple in vitro and in vivo preclinical models, KZR-261 has shown broad tumor growth inhibition including tumors resistant to traditional chemotherapeutics. The direct anti-tumor effect of KZR-261 is driven by induction of cell death through proteotoxic stress and other factors, as well as the reduced expression of key growth factors and receptors driving tumor survival and proliferation. In addition, KZR-261 modulates the tumor microenvironment by reducing angiogenic factor expression (e.g., VEGF) and reducing immune checkpoint expression. The preclinical data generated with KZR-261 increases our belief that inhibiting the Sec61 translocon could be effective against a variety of solid and hematologic tumor types.

We are conducting an open-label Phase 1 clinical trial of KZR-261 in patients with solid tumor malignancies. The study is being conducted in two parts: dose escalation in any solid tumor, and dose expansion in tumor-specific solid tumors. The study is designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, identify a recommended Phase 2 dose and explore the preliminary anti-tumor activity of KZR-261 in patients with locally advanced or metastatic disease. To date, we have enrolled a total of 35 patients and completed rapid dose escalation without significant safety concerns. KZR-261 has shown dose-proportional exposure, no signs of accumulation or altered pharmacokinetics with repeated dosing, and a half-life of greater than 25 hours with measurable levels at day 8, indicating continuous exposure with weekly dosing. As of March 2024, the dose escalation portion of the study is enrolling Cohort 9 (80 mg/m2). We plan to provide a data update from this trial by the end of 2024.

KZR-261 was discovered from our novel platform targeting the Sec61 translocon and the protein secretion pathway. We have highlighted our research 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. In October 2023, we paused our preclinical research and drug discovery activities on the protein secretion pathway to focus resources on clinical development of zetomipzomib and KZR-261.

License and Collaboration Agreements

License Agreement with Onyx

In June 2015, we entered into an exclusive license agreement with Onyx Therapeutics, Inc., or Onyx, a wholly owned subsidiary of Amgen, or 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 zetomipzomib, 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. Patent coverage for zetomipzomib extends to at least 2034.

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 in June 2018.

We have paid $5.0 million in milestone payments to date under the Onyx License Agreement, and we are obligated to pay Onyx additional milestone payments of up to $167.5 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 2027-2034, 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 Onyx 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.

Collaboration and License Agreement with Everest Medicines

In September 2023, we entered into a collaboration and license agreement, or the Everest License Agreement, with Everest Medicines II (HK) Limited, or Everest, pursuant to which, among other things, we granted an exclusive license to Everest to develop and commercialize one or more products containing zetomipzomib in the licensed field in the Greater China region (Mainland China, Taiwan, Hong Kong and Macau), South Korea, Singapore, Malaysia, Thailand, Indonesia, Vietnam and the Philippines. The licensed field includes all uses other than the diagnosis or treatment in humans of cancerous or pre-cancerous diseases or conditions.

Under the terms of the Everest License Agreement, we received an initial upfront payment of $7.0 million in October 2023, and we are entitled to receive milestone payments upon achievement of certain development, regulatory and commercial milestone events, for total potential milestone payments of up to $125.5 million. In addition, Everest will pay us tiered royalties on net sales of zetomipzomib in the licensed territory during the term of the Everest License Agreement, ranging from the single digit to the low-teens, subject to certain reductions for patent expiration, generic competition and payments for licenses to third-party patents.

The term of the Everest License Agreement will continue on a market-by-market basis until expiration of the relevant royalty term of the products, unless terminated earlier. Everest has the right to terminate the Everest License Agreement for convenience following completion, suspension or termination of the PALIZADE clinical trial. We may terminate the Everest License Agreement if Everest challenges our patents or fails to perform any development or commercialization activities for a continuous period of more than twelve months, subject to certain exceptions. In addition, either party may terminate the Everest License Agreement for the other party's uncured breach or insolvency, and the Everest License Agreement will automatically terminate in the event of termination of the Onyx License Agreement.

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 zetomipzomib 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 expect to utilize 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 zetomipzomib 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 zetomipzomib as a lyophilized product candidate, meaning it is freeze-dried and must be reconstituted with water prior to delivery to a patient. In our clinical trials, zetomipzomib is reconstituted in the hospital pharmacy prior to patient administration or reconstituted and self-administered by the patient at home. We intend that if approved and commercialized, zetomipzomib 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 one company currently engaged in drug discovery and development of selective inhibitors of the immunoproteasome. IpiNovyx Bio, founded in 2021, is engaged in preclinical research focused on small molecule immunoproteasome therapies for the treatment of autoimmune and inflammatory diseases.

Currently, SLE is treated with corticosteroids and immunosuppressive agents such as azathioprine. Current guidance for the treatment of proliferative LN 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 LN: Benlysta® (belimumab), an anti-BAFF monoclonal antibody from GlaxoSmithKline is approved for the treatment of moderate to severe SLE and LN; and Lupkynis™ (voclosporin), a calcineurin inhibitor from Aurinia Pharmaceuticals, is approved for the treatment of active LN, in each case in combination with a background immunosuppressive therapy regimen.

Other companies are developing agents to treat both SLE and LN. These agents include antibodies against the interferon alpha receptor, such as Saphnelo® (anifrolumab) from AstraZeneca, against IL-17, such as Cosentyx® (secukinumab), or BAFF, such as ianalumab, both under evaluation by Novartis, against CD20, such as Gazyva® (obinutuzimab) from Roche, and small molecule agents targeting TYK2, such as Sotyktu™ from Bristol Meyers Squibb, and JAK1, such as Rinvoq™, from Abbvie. In addition, adoptive cellular therapies such as CD19 and BCMA targeting chimeric antigen receptor (CAR)-T cells are being investigated by several companies for the treatment of SLE.

We are aware of one company engaged in drug discovery and development of small molecule drugs targeting the Sec61 translocon. Gate Bioscience, founded in 2021, is engaged in preclinical research focused on small molecule drugs for selectively eliminating harmful extracellular proteins via the secretary translocon.

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 intellectual property related to our business.

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

In total, our patent portfolio, including patents licensed from Onyx, comprises more than 10 different patent families, filed in various jurisdictions worldwide, including families directed to composition of matter for selective immunoproteasome inhibitors and protein secretion inhibitors. Our patent portfolio includes issued patents in, among other jurisdictions, the United States, Australia, Canada,

China, Europe, Japan, Mexico, Singapore and South Korea with expiration dates ranging from 2034 to 2039, absent any patent term extensions available.

Zetomipzomib

Our patent portfolio relating to zetomipzomib is outlined below:

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 zetomipzomib and its closely related analogs. 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 zetomipzomib. We have issued patents in numerous jurisdictions, including the United States, Australia, Chile, Eurasia, Japan, Mexico, and Taiwan. 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 zetomipzomib, including the clinical salt form. We have issued patents in numerous jurisdictions, including the United States, Australia, Chile, Eurasia, Japan, Mexico, and Taiwan. The 20-year term for this family is June 2037, absent any patent term extensions available.

KP-00-006—Patent application directed to combination of zetomipzomib and immunomodulator drugs, such as mycophenolate mofetil, for the treatment of lupus, lupus nephritis and other autoimmune diseases. We have issued patents in China and Japan. The 20-year term of this family is August 2038, absent any patent term extensions available.

KP-00-008—Patent application directed to formulations of zetomipzomib is pending, with an issued patent in Taiwan. The 20-year term of this family is October 2039, absent any patent term extensions available.

We expect to 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.

KZR-261

We have filed composition of matter patent applications directed to numerous protein secretion modulators and covering our current clinical candidate, KZR-261, with patents issued in the United States, Europe, Eurasia, Mexico, and Taiwan. The 20-year term of this family is March 2039, absent any patent term extensions available. We expect to continue to file applications directed to patentable aspects of KZR-261 as part of our ongoing research 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 our risk factors under Part I. Item 1A titled “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 Investigational New Drug Application, or 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 a New Drug Application, or 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 a specific timeframe to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

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

Progress reports detailing the results of the clinical trials must be submitted, at least annually, to the FDA, and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements, or if the drug has been associated with unexpected serious harm to patients.

Marketing Approval

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

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

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

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

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

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCP requirements.

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

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

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

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant ODD to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000, there is no reasonable expectation that sales of the drug in the United States will be sufficient to offset the costs of developing and making the drug available in the United States. ODD must be requested before submitting an NDA. ODD does not convey any advantage in or shorten the duration of the regulatory review and approval process.

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

Special FDA Expedited Review and Approval Programs

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

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

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

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

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

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

Post-Approval Requirements

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

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

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and

these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

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

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label, although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Drug Supply Chain Security Act to ensure accountability in distribution.

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

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

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

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

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

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal civil and criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

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

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

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

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

Privacy and Data Security

In the ordinary course of our business, we may process personal or sensitive data. Accordingly, we are, or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, industry standards, and other obligations related to data privacy, security, and protection. Such obligations may include, without limitation, the

Federal Trade Commission Act, the Telephone Consumer Protection Act of 1991, the California Consumer Privacy Act of 2018, the European Union's General Data Protection Regulation 2016/679, or EU GDPR, the EU GDPR as it forms part of United Kingdom ("UK") law by virtue of section 3 of the European Union (Withdrawal) Act 2018, or UK GDPR. In addition, various other states within the United States have enacted or proposed data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the EU GDPR applies to any company established in the European Economic Area, or EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; complying with specific requirements to process health-rated data; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authorities and affected individuals; and mandating the appointment of representatives in the UK and/or the EEA in certain circumstances.

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

Coverage and Reimbursement

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

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

Impact of Healthcare Reform on our Business

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

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

The PPACA became law in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers. Among other measures that may have an impact on our business, the PPACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Additionally, the PPACA extends manufacturers' Medicaid rebate liability, expanded eligibility criteria for Medicaid programs, and expands entities eligible for discounts under the Public Health Service pharmaceutical pricing program. There have been executive, judicial and Congressional challenges to certain aspects of the PPACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible the PPACA will be subject to judicial or congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the PPACA.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, then President Obama signed into law the Budget Control Act of 2011, as amended, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and, following passage of subsequent legislation, including the BBA, will continue until 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. In January 2013, the American Taxpayer Relief Act of 2012 was enacted and, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and

biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program, or SIP, proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

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. We cannot predict the full impact the longer-term shift towards value-based reimbursement will have on any of our product candidates in either the Medicare program, or in any other third-party payor programs that may similarly tie payment to provider quality.

We expect additional healthcare reform initiatives to be adopted in the future. We also expect these initiatives to increase pressure on drug pricing.

Foreign Regulation

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

Environmental, Social and Governance

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

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

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

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

Employees and Human Capital Resources

As of December 31, 2023, we had 58 full-time employees, 39 of whom were primarily engaged in research and development activities and 14 of whom had an M.D. or Ph.D. degree. None of our employees is represented by a labor union and we consider our employee relations to be good. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of equity-based compensation awards and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate Information

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

Available Information

Our website address is www.kezarlifesciences.com. We make available on our website, free of charge, our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov. The information found on our website is not incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

Item 1A. Risk Factors.

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

Summary of Selected Risks Associated with our Business

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

- We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.
- We have a limited operating history and have never generated revenue from product sales, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We will require substantial additional capital to finance our operations, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, reduce or terminate certain of our product development programs or other operations.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.
- Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of zetomipzomib and KZR-261, as well as any future product candidates.
- We may explore strategic collaborations, which would require us to relinquish important rights to and control over the development and commercialization of our product candidates to any future collaborators.
- Success in preclinical studies or earlier clinical trials may not be indicative of future clinical trial results, and we cannot assure you that any clinical trials will lead to results sufficient for the necessary regulatory approvals.
- Clinical trials are very expensive, time consuming and difficult to design and implement.
- 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.
- We may encounter substantial delays or difficulties in enrolling and retaining patients in our clinical trials.
- The manufacture of our product candidates is complex and uncertain, and until we develop a validated manufacturing process, we may encounter difficulties in supplying our planned and future clinical trials. If we encounter such difficulties, or fail to meet quality standards, our ability to meet clinical timelines and expand our development strategy could be impacted.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.
- We may not be able to obtain or maintain orphan drug designations or exclusivity for our product candidates, which could limit the potential profitability of our product candidates.
- Even if our product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.
- We face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.

- We are dependent upon Everest for the further development and commercialization of zetomipzomib in the greater China region, South Korea and certain Southeast Asian countries.
- Our relationships with customers, physicians, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, transparency laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.
- We rely on third parties to manufacture clinical supplies of our product candidates and to conduct, supervise and monitor our clinical trials and preclinical studies. If those third parties perform in an unsatisfactory manner, it may harm our business.
- Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach our exclusive license agreement with Onyx Therapeutics, Inc., we could lose the ability to continue the development and commercialization of zetomipzomib.
- If we are unable to obtain and maintain patent protection for zetomipzomib, KZR-261 or any future product candidate, if the scope of patent protection is not sufficiently broad, or if our patents are insufficient to protect our product candidates for an adequate amount of time, we may not be able to compete effectively in our markets.
- Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.
- We are highly dependent on the services of our executive officers, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.
- 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.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

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 $101.9 million, $68.2 million and $54.6 million for the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, we had an accumulated deficit of $350.8 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 zetomipzomib, KZR-261 and future product candidates from our protein secretion program;
- seek to discover and develop additional product candidates, including preclinical studies and clinical trials for such product candidates;
- maintain, protect and expand our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- seek marketing approvals for zetomipzomib, 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 zetomipzomib, 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 and our operations to date have been largely focused on raising capital and conducting preclinical and clinical development of zetomipzomib and KZR-261, as well as research and discovery activities of future product candidates under our protein secretion program. As an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization of our product candidates. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with any future collaborative partners, to successfully complete the development of and obtain the regulatory approvals necessary to commercialize zetomipzomib, 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 zetomipzomib, KZR-261 and any future product candidates;
- obtaining regulatory approvals for zetomipzomib, 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 zetomipzomib, a self-administered dual-chamber system for administering zetomipzomib 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 zetomipzomib, KZR-261 and any future product candidates, if approved;
- obtaining market acceptance, if and when approved, of zetomipzomib, 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, spin-off or other arrangements into which we may enter and performing our obligations pursuant to such arrangements;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- securing appropriate pricing in the United States and internationally.

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

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

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

As of December 31, 2023, we had cash, cash equivalents and marketable securities of $201.4 million. We believe that our existing cash, cash equivalents and marketable securities as of December 31, 2023 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 macroeconomic uncertainties and geopolitical tensions, 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 the adverse global economic conditions, including higher inflation rates and changes in interest rates, persist or worsen, we could experience an inability to access additional capital or engage in strategic transactions on terms reasonable to us, or at all.

We do not currently have any commitments for future funding other than reimbursement, milestone and royalty payments we may receive under our Everest License Agreement, and we may not receive any further funds under that agreement. In any event, we will require substantial additional capital to develop a delivery system for zetomipzomib, conduct additional clinical trials, seek regulatory approval and commence commercialization of zetomipzomib, KZR-261 or any future product candidates. Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize zetomipzomib, KZR-261 and any future product candidates.

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

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. In December 2021, we entered into Sales Agreement, or the ATM Agreement, with Cowen and Company, LLC, for an at-the-market offering program that allows us to sell up to an aggregate of $200 million of our common stock. As of December 31, 2023, approximately $68.3 million remains available under the at-the-market program. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. In addition, we may issue equity or debt securities as consideration for obtaining rights to additional compounds.

Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could negatively impact our ability to conduct our business. For example, our obligations under the Loan Agreement are secured by a security interest in all of our assets, other than our intellectual property which is subject to a negative pledge. In addition, the Loan Agreement contains customary covenants that, subject to specific exceptions, restrict our ability to, among other things, declare dividends or redeem or repurchase equity interests, incur additional liens, make loans and investments, incur additional indebtedness, engage in mergers, acquisitions and asset sales, transact with affiliates, undergo a change in control, add or change business locations, or engage in businesses that are not related to its existing business.

In addition, if we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. For example, in September 2023, we entered into a collaboration and license agreement with Everest granting it an exclusive license to develop and commercialize zetomipzomib in the greater China region, South Korea and certain Southeast Asian countries in exchange for an upfront payment and potential milestone and royalty payments.

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

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

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

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

We are required and expect to make significant payments in connection with our license agreement with Onyx Therapeutics, Inc., or Onyx, for zetomipzomib.

We acquired rights to zetomipzomib, 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. We have paid $5.0 million in milestone payments to date under the Onyx License Agreement, and we are obligated to pay Onyx additional milestone payments of up to $167.5 million in the aggregate upon the achievement of certain development, regulatory and sales milestones. In addition, we are obligated to pay Onyx tiered royalties based on net sales of zetomipzomib. 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 beginning on or prior to December 31, 2017 are permitted to be carried forward for only 20 years under applicable U.S. tax law. Our federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to federal law with respect to the limitations on the use of NOLs.

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

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

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, our suppliers, manufacturers, or our customers, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

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 zetomipzomib and KZR-261. 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 and 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 zetomipzomib or KZR-261 in the United States or abroad until we receive regulatory approval from the FDA or the applicable foreign regulatory authority.

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

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

We have invested a significant portion of our time and limited financial and management resources in the development of zetomipzomib and KZR-261. Our business is dependent on our ability to successfully complete development of, obtain regulatory

approval for, and, if approved, successfully commercialize zetomipzomib and KZR-261 in a timely manner. Our resource allocation decisions may cause us to fail to capitalize on profitable market opportunities for our product candidates.

Even if we eventually complete clinical testing and receive approval of a new drug application, or NDA, or foreign marketing application for zetomipzomib, 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, 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, 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 zetomipzomib, KZR-261 and any future product candidates, we may not be able to generate sufficient revenue to continue our business.

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

Our product candidates will require clinical testing before we are prepared to submit an NDA for regulatory approval. The clinical trial process is expensive, time consuming, difficult to design and implement, and subject to uncertainty. 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. Failure can occur at any stage, and we could encounter problems that cause us to suspend, abandon or repeat clinical trials.

PALIZADE is a global, placebo-controlled, double-blind Phase 2b clinical trial evaluating zetomipzomib in patients with LN. As an organization, we have not previously conducted a clinical trial to the scale of the PALIZADE trial. We have engaged and intend to use a single contract research organization, or CRO, to manage the PALIZADE trial, and although we will oversee their performance and maintain certain regulatory responsibilities, the ultimate success of initiating, enrolling and completing this trial, and ensuring regulatory and quality compliance across several countries, will depend significantly on the CRO's performance, in addition to several other third-party service providers and clinical trial vendors in the United States and worldwide.

We plan to conduct the PALIZADE trial in several countries where we have not previously engaged with local regulatory authorities nor performed clinical trials. The process and timelines required to obtain approval from foreign regulatory authorities is unpredictable and may depend upon numerous factors and their substantial discretion. The inability to obtain and maintain regulatory approval for the conduct of the PALIZADE trial outside the United States may impact the timelines and completion of the PALIZADE trial.

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

We currently focus our drug development of zetomipzomib on treatments of immune-mediated diseases, including lupus nephritis and autoimmune hepatitis. Our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product candidates. Our projections of both the number of people who have these disorders, as well as the subset of

people with these disorders who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these disorders. Our Phase 1 trial of KZR-261 is designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, and we have not yet selected the tumor types or patient populations for the next stages of clinical development. The number of eligible patients for either product candidate may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates. If the market opportunities for our product candidates are smaller than we estimate, our business and results of operations could be adversely affected.

Due to the significant resources required for clinical development, we are required to make strategic decisions for the development of our product candidates. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on other opportunities that may be more profitable or for which there may be a greater likelihood of success.

The development of zetomipzomib and KZR-261 requires significant capital investment. Due to the significant resources required for clinical development, we must focus our research and development efforts on specific indications and decide which development opportunities to pursue and advance for each program. Our decisions concerning the allocation of development, management and financial resources may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we do not accurately evaluate the viability, development costs and commercial potential of our product candidates, we may fail to capitalize on profitable market opportunities, forego or delay opportunities to pursue other product candidates or other indications that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to product candidates through strategic transactions, including collaboration, licensing or other royalty arrangements, asset sales, and spin-offs, in cases in which it would have been more advantageous for us to retain ownership and sole development and commercialization rights to such product candidates.

We may explore strategic collaborations, which would require us 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. For example, in September 2023, we entered into a collaboration and license agreement with Everest granting it exclusive license to develop and commercialize zetomipzomib in the greater China region, South Korea and certain Southeast Asian countries in exchange for an upfront payment and potential milestone and royalty payments. 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. 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 or slower than if we were doing so;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;

- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

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

Success in preclinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and early clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical studies and earlier clinical trials does not ensure that later trials designed to test efficacy will be successful, nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through earlier clinical trials. For example, in May 2022, we reported topline data from our PRESIDIO Phase 2 clinical trial of zetomipzomib in patients with dermatomyositis and polymyositis, in which zetomipzomib did not demonstrate significant differentiation from placebo.

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.

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 zetomipzomib to address several autoimmune diseases with high degrees of unmet medical need, including lupus nephritis and autoimmune hepatitis. If the actual number of patients with these disorders is smaller than we anticipate, or if these patients are unwilling to participate in a clinical trial, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our product candidates. 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, our ability to provide zetomipzomib for at-home administration, 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, political instability or disruption in a geographic region where we are conducting trials, regardless of cause, including public health crises, war, terrorism, social unrest and political changes, could delay or prevent patients from enrolling or from receiving treatment in accordance with the protocol and the required timelines, which could delay our clinical trials, or prevent us from completing our clinical trials at all. Any inability to timely and successfully complete clinical development will increase our costs, slow our development plans and impair our ability to generate revenue from our product candidates. In addition, we may be reliant on CROs and clinical 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.

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

We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the FDA or a comparable foreign regulatory authority, and we may never receive such approvals. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. A failure of one or more clinical trials can occur at any stage of testing. For example, in May 2022, we reported topline data from our PRESIDIO Phase 2 clinical trial of zetomipzomib in patients with dermatomyositis and polymyositis, in which zetomipzomib did not demonstrate significant differentiation from placebo. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Moreover, circumstances may arise that could result in suspending or terminating our ongoing clinical trials. As an example, some patients included in the MISSION Phase 2 clinical trial were located in Ukraine and Russia at the time of the Russian invasion of Ukraine. The closure of sites, the inability to screen and enroll new patients or any premature discontinuation of treatment by patients already enrolled in our trial could result in the need to enroll additional patients, which would be costly and could delay our anticipated timeline for the completion of the trial. Any inability to timely and successfully complete clinical development will increase our costs, slow our development plans and impair our ability to generate revenue from our product candidates.

We have experienced and may in the future 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:

- 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;
- delays in manufacturing, testing, releasing, validating and shipping stable quantities of our product candidates and placebo for our clinical trial sites;
- delays in reaching a consensus with the FDA and foreign regulatory authorities on the design of our clinical trials;
- the number of patients required for clinical trials to produce statistically meaningful data may be larger than we anticipate;
- the costs of clinical trials of our product candidates may be greater than we anticipate, which may be more likely as a result of increased price inflation worldwide;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- 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;
- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site, or may otherwise suspend our clinical trials at any time if it appears we are or our collaborators are failing to conduct a trial in accordance with regulatory requirements;
- 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, such as the topline data from our PRESIDIO Phase 2 clinical trial of zetomipzomib in patients with dermatomyositis and polymyositis, in which zetomipzomib did not demonstrate significant differentiation from placebo;
- failure to perform our clinical trials in accordance with current Good Clinical Practice, or cGCP, or regulations required by the FDA or foreign regulatory authorities;
- changes in regulatory requirements and guidance or other unforeseen regulatory developments that require amending or submitting new clinical protocols;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; or
- business interruptions resulting from geo-political actions, war, terrorism, natural disasters or public health crises.

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

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

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

Further, we, the FDA, comparable foreign regulatory authorities, or an IRB may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including cGCP, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our INDs, or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of 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.

The manufacture of our product candidates is complex and uncertain, and until we develop a validated manufacturing process, we may encounter difficulties in supplying our planned and future clinical trials. If we encounter such difficulties, or fail to meet quality standards, our ability to meet clinical timelines and expand our development strategy could be impacted.

The processes involved in manufacturing the active drug substance and finished drug product of zetomipzomib and KZR-261 are complex, expensive, highly regulated and subject to multiple risks and uncertainties. As product candidates are developed through early to late-stage clinical trials and then to approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are modified along the way to optimize the scale, process and results. Any changes to the manufacturing processes carry the risk that they will not achieve these intended objectives, or that the product candidates may not meet the rigorous quality standards necessary for use in our clinical trials.

We are continuing to manufacture zetomipzomib and placebo in support of our PALIZADE and PORTOLA trials. However, if planned or future manufacturing of zetomipzomib fails to meet the quality standards for use in our clinical trials, or the active drug substance does not meet our quality specifications, it could impact our timelines and limit our development strategy.

In addition, our contract manufacturing organizations, or CMOs, may be unable to successfully increase the manufacturing scale for our product candidates in a timely or cost-effective manner and may experience delays due to limited manufacturing capacity. In addition, quality issues may arise during manufacturing activities. If our CMOs are unable to successfully manufacture our product candidates in sufficient quantity in a timely manner, our planned clinical trials may be delayed or modified and we may also be unable to fulfill our obligations under the Everest License Agreement, giving rise to the ability of Everest to terminate its collaboration or other potential adverse consequences as provided in the Everest License Agreement.

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

Zetomipzomib has been involved in an investigator-initiated clinical trial, and our product candidates may be involved in investigator-initiated clinical trials in the future. Investigator-initiated clinical trials pose similar risks as those set forth elsewhere in this "Risk Factor" section relating to our own internal clinical trials. However, while investigator-initiated clinical trials may provide us with

clinical data that can inform our development strategy, we are not the sponsors of such trials, and therefore, we do not control the protocols, administration, quality or conduct of these trials, including follow-up with patients and ongoing data collection. Despite this lack of control, negative results in investigator-initiated clinical trials could have a material adverse effect on our business and prospects and the perception of our product candidates.

Interim topline 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 topline 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 topline 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 topline 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.

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

We are developing zetomipzomib 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 zetomipzomib could adversely affect market acceptance and make it more difficult to conduct clinical trials of zetomipzomib. In our current trials, zetomipzomib is reconstituted in the hospital pharmacy prior to patient administration or reconstituted and self-administered by the patient at home.

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

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, discomforts and other adverse events, to their doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur. In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects or patients. Many times, side effects are only detectable after investigational drugs are tested in large-scale pivotal trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that zetomipzomib, KZR-261 or any future product candidates has side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition.

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

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

- regulatory authorities may not permit us to initiate our studies or could put them on hold;
- regulatory authorities may not approve, or may withdraw, their approval of the product;
- regulatory authorities may require us to recall the product;
- regulatory authorities may add new limitations for distribution and marketing of the product;

- regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered or modify the product in some other way;
- we may be required to implement a REMS program;
- the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000, there is no reasonable expectation that sales of the drug in the United States will be sufficient to offset the costs of developing and making the drug available in the United States. If a drug with an orphan drug designation subsequently receives the first marketing approval for use in the rare disease or condition for which it was designated, then the sponsor is eligible for a seven-year period of marketing during which the FDA may not approve another sponsor's marketing application for a drug with the same active moiety and intended for the same use or indication as the approved orphan drug, except in limited circumstances, such as if a subsequent sponsor demonstrates its product is clinically superior. During a sponsor's orphan drug exclusivity period, however, competitors may receive approval for drugs with different active moieties for the same indication as the approved orphan drug, or for drugs with the same active moiety as the approved orphan drug, but for different indications. 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.

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

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

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of zetomipzomib and KZR-261 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 zetomipzomib and KZR-261 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 zetomipzomib, KZR-261 and any future product candidates in certain countries.

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

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

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

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

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory authority may:

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

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

The FDA's and comparable foreign regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we

may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

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

Even if our product candidates receive marketing approval, they may fail to gain market acceptance by physicians, patients, third-party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of zetomipzomib, 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.

We are dependent upon our collaboration with Everest to further develop and commercialize zetomipzomib in the Greater China region, South Korea and select Southeast Asian countries. If we or Everest fail to perform as expected, the potential for us to generate future revenues under the collaboration could be significantly reduced, the development and commercialization of zetomipzomib may be substantially delayed, and our business could be adversely affected.

In September 2023, we entered into the Everest License Agreement granting Everest an exclusive license to develop and commercialize zetomipzomib in the greater China region, South Korea, and select Southeast Asian countries. Under the terms of the Everest License Agreement, we received an initial upfront payment of $7.0 million and are entitled to receive milestone payments upon achievement of certain development, regulatory and commercial milestone events, for total potential milestone payments of up to $125.5 million. In addition, Everest will pay to the Company tiered royalties on the net sales of zetomipzomib in the Territory during the term of the Everest License Agreement ranging from the single digit to the low-teens, subject to certain reductions.

Everest will be responsible for, at its own cost, and is required to use commercially reasonable efforts to, develop and commercialize zetomipzomib in the licensed territory. In addition, we will collaborate with Everest on the PALIZADE trial, where Everest will have primary responsibility for clinical development and regulatory activities in the licensed territory and will reimburse the Company for clinical trial costs incurred in the licensed territory. Everest will also have the opportunity to participate in the Company's future global clinical trials involving zetomipzomib. The Company has agreed to supply zetomipzomib to Everest during the term of the Everest License Agreement, subject to Everest's option to manufacture zetomipzomib for its own use in the licensed territory following completion of the PALIZADE trial.

There can be no assurance that the parties will achieve any of the regulatory, development or sales milestones, or that we will receive any future milestone or royalty payments under the Everest License Agreement. Everest's activities may be influenced by, among other things, the efforts and allocation of resources by Everest, which we cannot control. If Everest does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, manufacturing, regulatory approval, and commercialization efforts related to zetomipzomib could be substantially delayed.

In addition, our collaboration with Everest may be unsuccessful due to other factors, including, without limitation, the following:

- Everest may terminate the agreement for convenience following completion, suspension or termination of the PALIZADE trial;
- Everest may change the focus of its development and commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to zetomipzomib;
- Everest may, within its commercially reasonable discretion, choose not to develop and commercialize zetomipzomib in any part of the licensed territory or for one or more indications, if at all; and
- If Everest is acquired during the term of our collaboration, the acquirer may have competing programs or different strategic priorities that could cause it to reduce its commitment to our collaboration or to terminate the collaboration.

The actions of Everest and any other current or future licensees could adversely affect our business.

We currently exclusively license zetomipzomib to Everest to develop and commercialize zetomipzomib in the greater China region, South Korea and select Southeast Asian countries. It is possible that any clinical trials conducted by Everest or any other current or future licensees in its respective licensed territories could have negative results, which in turn could have a material adverse effect on the development and commercialization of zetomipzomib in the United States and the rest of the world. In addition, we will depend on Everest or any other current or future licensee to comply with all applicable laws relative to the development and commercialization of zetomipzomib in its respective licensed territories. If Everest were to violate, or was alleged to have violated, any laws or regulations during the performance of its obligations to us, it is possible we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences. In addition, in the event of any termination, breach or expiration of the Everest License Agreement, we may be required to devote additional efforts and to incur additional costs associated with pursuing the development and commercialization of zetomipzomib in the greater China region, South Korea and select Southeast Asian countries.

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, medical, 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.

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

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

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

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

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

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

Coverage and adequate reimbursement may not be available for zetomipzomib or KZR-261, 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 zetomipzomib, KZR-261 or any future product candidates that we develop. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 as we advance through clinical development and if we are able to successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Regulatory Compliance

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, formulary managers and others, on the other hand. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation;

- federal civil and criminal false claims laws, including, without limitation, the federal civil False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, implicate the federal civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal civil and criminal statutes that prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program, or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information on health plans, health care clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates and their subcontractors that perform certain services involving the use or disclosure of individually identifiable health information;
- federal transparency laws, including the federal Physician Payments Sunshine Act, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (i) payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws, state laws that require manufacturers to report information related to payments and other "transfers of value" to physicians and other healthcare providers, marketing expenditures, or drug pricing, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and state and local laws that require the registration of pharmaceutical sales representatives, or that otherwise restrict payments that may be made to healthcare providers; as well as state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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

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

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

Since its passage, there have been varied executive, judicial and Congressional challenges to certain provisions of the PPACA. In addition, Congress has considered, and may consider in the future, legislation to repeal or repeal and replace all or part of the PPACA. While Congress has not passed any comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the PPACA have been signed into law. On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the PPACA and our business.

Other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2032 unless additional congressional action is taken. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which included a number of significant drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services, or HHS, that would require pharmaceutical manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation, and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs and Part D beneficiaries' annual out-of-pocket spending will be capped at $2,000 beginning in 2025, although the Medicare drug price negotiation program is currently subject to legal challenges. The U.S. Department of Health and Human Services has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although they may be the Medicare drug price negotiation program is currently subject to legal challenges. It is unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

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. Under the Quality Payment Program,

performance data collected each performance year will affect Medicare payments in later years, including potentially reducing payments.

Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices and directed HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether these this executive order or similar policy initiatives will be implemented in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

Risks Related to Our Dependence on Third Parties

We will rely on third parties to manufacture clinical and commercial supplies of zetomipzomib, 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. Moreover, under the Everest License Agreement, we have committed to providing Everest with supply of zetomipzomib for the development and commercialization of zetomipzomib in the greater China region, South Korea and certain Southeast Asian countries, which we will have to source from third-party manufacturers. 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 or cause us to breach our obligations under the Everest License Agreement. We are completely dependent on our CMOs for compliance with cGMP for manufacture of both active drug substances and finished drug products. If our CMOs cannot successfully manufacture active drug substances and finished drug product that conform to our specifications and the strict regulatory requirements of the FDA and comparable foreign regulatory authorities, we will not be able to secure or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our timelines and ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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

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

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- our third-party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our third-party manufacturers may fail to comply with cGMP and other inspections by the FDA or comparable foreign regulatory authorities;

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

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

We rely on third parties to conduct, supervise and monitor our clinical trials and preclinical studies, 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 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. For example, we have engaged and intend to use a single CRO to manage the PALIZADE trial, and although we will oversee their performance and maintain certain regulatory responsibilities, the ultimate success of initiating, enrolling and completing this trial, and ensuring regulatory and quality compliance across several countries, will depend significantly on the CRO's performance.

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

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

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

These factors may materially adversely affect the timelines of our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, fail to comply with regulatory requirements, or if the quality or accuracy of the clinical data they obtain is compromised

due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, the product candidate being developed. As a result, our financial results and commercial prospects would be harmed, our costs could increase, and our ability to generate revenue from the product candidate could be delayed. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities which could compete with recruitment of our clinical trials.

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

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

Risks Related to Our Intellectual Property

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach the Onyx License Agreement, we could lose the ability to continue the development and commercialization of zetomipzomib.

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 zetomipzomib, 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 zetomipzomib, that are selective inhibitors of the immunoproteasome for any and all uses, other than those related to the diagnosis or treatment in humans of cancerous or pre-cancerous diseases or conditions, including those related to hematological diseases or conditions.

The licensed compounds, including zetomipzomib, are selective for the immunoproteasome and therefore are not known or believed, based on scientific literature and the Company's own research and development activities, to have any application in cancer or pre-cancerous conditions. However, notwithstanding these known characteristics of the licensed compounds, Onyx retains all rights under the licensed intellectual property rights that are not granted to the Company, and therefore Onyx retains rights under such intellectual property rights to develop and commercialize the licensed compounds in connection with the diagnosis or treatment in humans of cancerous or pre-cancerous diseases or conditions, including those related to hematological diseases or conditions, and also has the rights to transfer these rights to a third-party. If Onyx or its licensee develops and commercializes any of the licensed compounds in cancer or pre-cancerous indications that are commercially interchangeable with our product candidates, including zetomipzomib, sales by Onyx or its licensee of such compounds for cancer and pre-cancerous indications could result in the threat of off-label use in our licensed field, potentially diminishing our sales of the applicable licensed compounds in our licensed field.

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

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

- the scope of rights granted under the agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- our right to sublicense patent and other rights to third parties;

- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign our license; and
- the effects of termination.

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

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

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

If we are unable to obtain and maintain patent protection for zetomipzomib, 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 zetomipzomib, 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 zetomipzomib.

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 zetomipzomib, 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 zetomipzomib, 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 zetomipzomib, 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.

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 zetomipzomib 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.

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

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

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 zetomipzomib and KZR-261 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 zetomipzomib, 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 zetomipzomib, KZR-261 or any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Many companies and research institutions have filed, and continue to file, patent applications related to selective immunoproteasome inhibitors and protein secretion inhibitors. Some of these patent applications have already been allowed or issued, and others may issue in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes our product candidate infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties or other amounts. Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all.

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

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

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

the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

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

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

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

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

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

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

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

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

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential

information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us.

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

Since we rely on third parties to develop and manufacture zetomipzomib and KZR-261, and if we collaborate with third parties for the development of our research programs or product candidates, we must, at times, share trade secrets with them. We may also conduct collaborative research and development programs that may require us to share trade secrets and proprietary know how. We seek to protect our proprietary information by entering into agreements containing confidentiality obligations and ownership provisions relating to intellectual property prior to disclosing proprietary information or beginning research projects with third-party collaborators. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, sharing trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, the unauthorized disclosure or use of our confidential information could have an adverse effect on our business and results of operations.

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

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

Filing, prosecuting and defending patents covering zetomipzomib, KZR-261 and any future product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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

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

- others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents, should they issue, that we own or control;
- we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or control;
- we might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or control may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;

- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may prevent us from fully exploiting our product candidates or technologies.

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

We are highly dependent on the services of our executive officers, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

Recruiting and retaining 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.

Further, our Workforce Reduction announced in October 2023 may make retention of our current personnel both more important and more challenging. This Workforce Reduction resulted in the loss of certain longer-term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations.

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. This could be a particular challenge as a result of the Workforce Reduction announced in October 2023. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

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

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy,

security, and transmission of individually identifiable health information. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors). In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts. Additionally, in the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR and the United Kingdom's GDPR, or UK GDPR impose strict requirements for processing the personal data of individuals located, respectively within the European Economic Area, or EEA and the United Kingdom, or UK. For example, under GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros under the EU GDPR or 17.5 million pounds sterling under the UK GDPR, or, in each case, 4% of annual global revenue, whichever is greater. Further, companies may face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In Canada, the Personal Information Protection and Electronic Documents Act and various related provincial laws, as well as Canada's Anti-Spam Legislation, may apply to our operations.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Although there are various mechanisms that may be used in some cases to lawfully transfer personal data to the United States or other countries, these mechanisms are subject to legal challenges and may not be available to us. An inability or material limitation on our ability to transfer personal data to the United States or other countries could materially impact our business operations. In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security are quickly changing and are becoming increasingly stringent, and creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, including, without limitation, financial and time-related resources. These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with

all applicable data privacy and security obligations, we may at times fail, or be perceived to have failed, to do so, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation, including class-related claims and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations, including clinical trials; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

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

In the ordinary course of our business, we and the third parties upon which we rely process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets (collectively, sensitive information). Cyberattacks, malicious internet-based activity, and online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyberattacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third-party service providers to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident could disrupt our ability (and that of third parties upon whom we rely) to conduct our business. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

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

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Additionally, we cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and comparable foreign regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or comparable foreign regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. 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 has at times experienced price volatility and may continue to be volatile. For example, during 2023, the closing price of our common stock on The Nasdaq Global Select Market ranged from $7.31 per share to $0.72 per share. 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, 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, including higher inflation rates and changes in interest rates, and other adverse effects or developments, 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 zetomipzomib, 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;
- negative or inconclusive results from our clinical trials, such as the May 2022 topline data from the PRESIDIO Phase 2 clinical trial;
- 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 bank failures, public health crises or geopolitical tensions; 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.

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.

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

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, changes in interest rates and uncertainty about economic stability. For example, the Russia-Ukraine war and the Israel-Hamas war created volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of recent bank failures, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. A weak or declining economy could also strain our suppliers and

manufacturers, possibly resulting in supply and clinical trial disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

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

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

Based upon our shares of our common stock outstanding as of December 31, 2023, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock do, in the aggregate, beneficially own shares representing approximately 40% of our outstanding common stock. If our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock acted together, they may be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in the management of our company in ways with which other stockholders disagree.

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

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

We are a "smaller reporting company," and the reduced disclosure requirements applicable to such companies may make our common stock less attractive to investors.

We are a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended. We 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, we have incurred and will continue to incur significant legal, accounting, insurance, and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred and will continue to incur costs associated with the Sarbanes-Oxley Act and related rules implemented by the SEC and the Nasdaq Stock Market. Our management and other personnel will need to devote a substantial amount of time to compliance with these laws and regulations. These requirements have increased and will continue to increase our legal, accounting, external audit and financial compliance costs and have made and will continue to make some activities more time consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we assess and document the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, Section 404(a) of the Sarbanes-Oxley Act, or Section 404(a), requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. Section 404(b) of Sarbanes-Oxley Act, or Section 404(b), also requires our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement and maintain corporate governance practices and comply with reporting requirements. However, while we remain a smaller reporting

company that is not an accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

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, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. 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 1C. Cybersecurity.

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third-party hosted services, communications systems, hardware and software, and critical data, including intellectual property, clinical trial data, and other confidential information that is proprietary, strategic or competitive in nature ("Information Systems and Data").

The Company's Chief Financial Officer ("CFO"), Information Technology ("IT") manager, legal function and external information technology and cybersecurity service provider help to identify, assess and manage our cybersecurity threats and risks. They identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and our and our industry's risk profile using various methods, including, for example, automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors, conducting scans of the threat environment, evaluating threats reported to us, conducting internal audits, and conducting internal and external threat and vulnerability assessments.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example, an incident response plan, incident detection and response, a vulnerability management policy, business continuity plans, risk assessments, encryption of data, network security controls, access controls, asset management and disposal, physical security, systems monitoring, employee training, penetration testing, and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, our IT manager works with our management team to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business. Additionally, our management team evaluates material risks from cybersecurity threats against our overall business objectives and regularly reports to the Audit Committee of our board of directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including, for example, managed cybersecurity providers, cybersecurity software providers, penetration testing firms, and professional services firms, including legal counsel.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosted services, CROs, and CMOs. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, we may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part I. Item 1A titled "Risks Related to Our Business Operations, Employee Matters and Managing Growth."

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The Audit Committee of our board of directors is responsible for overseeing Company's cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our CFO and IT manager. Our CFO has overseen and been responsible for the Company's information technology and cybersecurity programs since 2018, and before that held equivalent responsibilities at another public company. Our IT manager has approximately seven years of experience with testing, implementing and maintaining our information technology systems and security.

Our CFO is responsible for hiring appropriate personnel, retaining third-party information technology service providers, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, communicating key priorities to relevant personnel and approving budgets. Our IT manager and our third-party information technology service provider are together responsible for helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response plan is designed to escalate certain cybersecurity incidents to key members of management depending on the circumstances. Our CFO works with the Company's IT manager and our third-party information technology service provider to help us mitigate and remediate cybersecurity incidents of which our CFO is notified. In addition, our incident response plan includes reporting to the Audit Committee of our board of directors for certain cybersecurity incidents.

The Audit Committee receives regular reports from our CFO concerning the Company's significant cybersecurity threats and risks, and the processes the Company has implemented to address them. The board of directors also has access to reports, summaries and presentations related to the Company's cybersecurity threats, risk and mitigation.

Item 2. Properties.

Our principal corporate offices are located in South San Francisco, California and consists of approximately 49,000 square feet of leased office and laboratory space, all of which is located in a single building, under a lease that expires in July 2026. 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.

Not Applicable.

PART II

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

Market Information

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

Holders

As of February 28, 2024, there were approximately 10 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

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

Recent Sales of Unregistered Equity Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved].

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

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

Overview

We are a clinical-stage biotechnology company 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 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, zetomipzomib, is a first-in-class selective immunoproteasome inhibitor that has completed Phase 1a testing in healthy volunteers and a Phase 1b/2 clinical trial in patients with SLE, with or without LN (the MISSION trial). We are conducting PALIZADE, a global, placebo-controlled, double-blind Phase 2b clinical trial evaluating zetomipzomib in patients with LN. In addition, we are leveraging the broad therapeutic potential of zetomipzomib in other severe autoimmune diseases of high unmet medical need. PORTOLA is a placebo-controlled, double-blind Phase 2a clinical trial evaluating zetomipzomib in patients with AIH. We are also continuing to explore development opportunities for zetomipzomib in patients with SLE.

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

Our oncology product candidate, KZR-261, is a small molecule agent being studied in an open-label Phase 1 clinical trial designed to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics, as well to explore preliminary anti-tumor activity. This study is being conducted in two parts: dose escalation in patients with locally advanced or metastatic solid malignancies, and dose expansion in patients with selected tumor types. KZR-261 was discovered from our novel research platform targeting the Sec61 translocon and the protein secretion pathway. KZR-261 has demonstrated broad anti-tumor activity in preclinical models of both solid and hematologic malignancies by targeting multiple pathways driving tumor growth and survival.

Since the commencement of our operations in 2015, we have devoted substantially all of our resources to performing research and development activities in support of our product development efforts, hiring personnel, raising capital to support and expand such activities and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily from the issuance and sale of convertible preferred stock, from public offerings of common stock and pre-funded warrants to purchase common stock as described below, and debt. We acquired exclusive worldwide rights to zetomipzomib 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 zetomipzomib 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 $101.9 million, $68.2 million and $54.6 million for the years ended December 31, 2023, 2022 and 2021, respectively, and we expect to continue to incur significant losses for the foreseeable future. As of December 31, 2023, we had an accumulated deficit of $350.8 million. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on 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.

Critical Accounting 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 the significant accounting policies are more fully described in Note 2 to our audited financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following critical accounting estimates are most important to understanding and evaluating our reported financial results.

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 determine the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with our internal personnel and external service providers as to the progress or stage of completion of trials or services for the services when we have not yet been invoiced or notified of the actual progress and cost. Any payments made in advance of services provided are recorded as prepaid assets, which are expensed as the contracted services are performed. 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. For the periods presented, we have experienced no material differences between our accrued expenses and actual expenses.

Financial Operations Overview

Collaboration Revenue

We have no products approved for commercial sale and, to date, have not generated any revenue from the sale of products, and we do not expect to generate any revenue from the sale of products in the near future. Our revenue to date has been generated from the upfront payment pursuant to our collaboration with Everest under the Everest License Agreement. We recognize collaboration revenue when the performance obligation is satisfied.

In addition to receiving the upfront payment, we may also be entitled to milestones and other contingent payments upon achieving predefined objectives. If a milestone being reached is considered probable, and if it is probable that a significant revenue reversal would not occur, the associated milestone amount would also be included in the transaction price.

We expect that any collaboration revenue we generate from the Everest License Agreement, and from any future collaboration partners, will fluctuate as a result of the timing and amount of upfront, milestones and other collaboration agreement payments and other factors.

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.

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

	Year Ended December 31,		
	2023	2022	2021
(dollars in millions)		(unaudited)	
Research and development expenses by program:			
Zetomipzomib	$ 56.1	$ 29.6	$ 24.6
KZR-261	15.6	11.5	7.8
Other protein secretion discovery programs	14.0	9.9	6.5
Total research and development expenses	$ 85.7	$ 51.0	$ 38.9

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

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel expenses, allocated facilities costs and fees for outside consulting and professional services, including legal, human resource, information technology and audit services. Personnel expenses consist of salaries, benefits and stock-based compensation. We will incur additional expenses as we increase the size of our administrative function to support the growth of our business.

Interest Income

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

Interest Expense

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

Restructuring and Impairment Charges

In October 2023, we announced a strategic restructuring and workforce reduction (the "Workforce Reduction") to prioritize our clinical-stage assets and extend our cash runway, reducing our workforce by approximately 40%. All employees affected by the Workforce Reduction were eligible to receive, among other things, severance payments and the continuation of group health insurance coverage for a specified time period post-termination.

In connection with the Workforce Reduction, we committed to a plan to sublease Suite 400 of our corporate headquarters, which resulted in an impairment to the right-of-use asset and certain property and equipment no longer utilized under current or expected future operations. We recognize 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. See Note 17 to our consolidated financial statements located elsewhere in this Annual Report on Form 10-K for additional information on the restructuring and impairment charges.

Results of Operations

A discussion regarding our financial condition and results of operations for the year ended December 31, 2022 compared to the year ended December 31, 2021 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, 2022, filed with the SEC on March 14, 2023.

Comparison of the Years Ended December 31, 2023 and 2022

(dollars in millions)	Year Ended December 31, 2023	2022	Increase (decrease)
Collaboration revenue	$ 7.0	$ —	$ 7.0
Operating expenses:			
Research and development	85.7	51.0	34.7
General and administrative	26.5	20.1	6.4
Restructuring and impairment charges	6.2	—	6.2
Total operating expenses	118.4	71.1	47.3
Loss from operations	(111.4)	(71.1)	(40.3)
Interest income	11.1	4.1	7.0
Interest expense	(1.6)	(1.2)	(0.4)
Net loss	$ (101.9)	$ (68.2)	$ (33.7)

Collaboration Revenue

Collaboration revenue increased by $7.0 million in 2023 compared to 2022 due to the upfront payment under the Everest License Agreement.

Research and Development Expenses

Research and development expenses increased by $34.7 million in 2023 compared to 2022. The increase was primarily due to an increase of $17.8 million in clinical trial costs primarily related to increased activities for the PALIZADE and PORTOLA trials, an increase of $5.4 million in research expenses primarily related to the milestone payment under Onyx License Agreement, an increase of $3.0 million in facility-related expenses due to the expansion of our headquarters, an increase of $2.4 million in personnel-related expenses due to increased headcount prior to the Workforce Reduction, an increase of $2.0 million in stock-based compensation primarily due to incremental expenses from the option repricing, an increase of $1.6 million in pre-clinical expenses related to the protein secretion program, an increase of $1.4 million in drug manufacturing expenses and an increase of $0.9 million in consulting expenses.

General and Administrative Expenses

General and administrative expenses increased by $6.4 million in 2023 compared to 2022. The increase was primarily due to an increase of $2.1 million in stock-based compensation primarily related to incremental expenses from option repricing, an increase of $1.6 million in personnel-related expenses due to increased headcount prior to the Workforce Reduction, an increase of $2.0 million in consulting and professional service fees in connection with the Everest License Agreement and business development activities, and an increase of $0.7 million in facility-related expenses primarily due to the expansion of our headquarters.

Restructuring and impairment charges

Restructuring and impairment charges increased by $6.2 million in 2023 compared to 2022. The increase was primarily related to one-time severance-related costs of $3.3 million and an impairment loss of $2.9 million due to the ROU asset and certain property and equipment no longer utilized.

Interest Income

Interest income increased by $7.0 million in 2023 compared to 2022. The increase was primarily attributable to higher cash equivalent and marketable securities balances and increased interest rates.

Interest Expense

Interest expense increased by $0.4 million in 2023 compared to 2022. The interest expense was composed of the contractual coupon interest expense, the amortization of the debt discount and issuance costs and the accretion of the final payment fee associated with the Oxford Loan Agreement.

Liquidity and Capital Resources

Overview

As of December 31, 2023, we had $35.5 million in cash and cash equivalents and $165.9 million of marketable securities invested in a U.S. Treasury money market fund, U.S. Treasury securities, U.S. agency bonds, commercial paper and certificate of deposit. As of December 31, 2023, our cash equivalents and marketable securities had a weighted average maturity of approximately six months and the longest maturity was 16 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 $101.9 million for the year ended December 31, 2023, and we had an accumulated deficit of $350.8 million as of December 31, 2023.

We believe that our existing cash, cash equivalents and marketable securities as of December 31, 2023 will be sufficient to meet our projected operating requirements through at least the next 12 months from the date the financial statements were issued. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

At-the-Market Offering Program

In December 2021, we entered into a Sales Agreement (the "December 2021 ATM Agreement") with Cowen and Company, LLC, or Cowen, pursuant to which we can offer and sell, from time to time at our sole discretion through Cowen, as our sales agent, shares of common stock having an aggregate offering price of up to $200.0 million. Any shares of common stock sold will be issued pursuant to our shelf registration statement on Form S-3. We will pay Cowen a commission equal to 3.0% of the gross sales proceeds of any shares of common stock sold through Cowen under the December 2021 ATM Agreement and also have provided Cowen with indemnification and contribution rights. As of December 31, 2023, we have sold an aggregate of 11,986,003 shares of our common stock for gross proceeds of approximately $131.7 million at a weighted average purchase price of $10.98 per share pursuant to the ATM Agreement. As of December 31, 2023, approximately $68.3 million remains available under the ATM Agreement.

Debt Facility

In November 2021, we entered into the Loan Agreement with Oxford Finance LLC, or Oxford Finance, which provided for up to $50.0 million in borrowing capacity across five potential tranches. The initial tranche of $10.0 million was funded at the closing of the Loan Agreement. The remaining tranches were dependent on achieving certain clinical trial milestones. As of December 31, 2023, we declined these tranches in borrowing capacity available to us under the Loan Agreement.

Until June 30, 2023, the Loan Agreement bore interest at a floating per annum rate (based on the actual number of days elapsed divided by a year of 360 days) equal to the sum of (a) the greater of (i) the 30-day U.S. LIBOR rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue and (ii) 0.08%, plus (b) 7.87%. We are required to make monthly interest-only payments prior to the amortization date of January 1, 2025, subject to a potential one-year extension upon satisfaction of certain conditions. The loan facility is secured by all assets except intellectual property, which is subject to a negative pledge, and will mature on November 1, 2026. There are no warrants or financial covenants associated with the Loan Agreement. A LIBOR transition event occurred effective July 1, 2023 and Oxford Finance revised the Loan Agreement to replace the LIBOR rate with the 1-month CME term SOFR plus 0.1%. The rate change did not require contract remeasurement at the effective date of the change or a reassessment of any previous accounting determinations pertaining to the facility. The rate change did not have a material impact on the Company's financial statements.

Funding Requirements

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

Our future funding requirements will depend on many factors, including the following:

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

- the costs of obtaining clinical and commercial supplies for zetomipzomib, KZR-261 and any other product candidates we may identify and develop;
- the cost, timing and outcomes of regulatory approvals;
- the extent to which we may acquire or in-license other product candidates and technologies;
- the cost of attracting, hiring and retaining qualified personnel;
- our ability to successfully commercialize any product candidates for which we obtain regulatory approval; and
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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

Our expected material cash requirements comprise of contractually obligated expenditures. Our material cash requirements through fiscal year 2027 are expected to total approximately $22.5 million, which includes debt payments, including principal, future interest payments and the final payment fee due on maturity, and amounts due under our operating leases. For additional information relating to our leases or debt, see notes 6 and 7 to our audited consolidated financial statements founded elsewhere in this Annual Report. We have no material non-cancelable purchase commitments with service providers, as we have generally contracted on a cancelable, purchase order basis. Our expected material cash requirements do 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. See the section titled “Business—License Agreement with Onyx” for additional information.

We will require additional financing to fund working capital and pay our obligations. We may pursue financing opportunities through a combination of equity offerings, debt financings and additional funding from license and collaboration agreements. Except for any obligations of Everest to reimburse us for research and development expenses or to make milestone or royalty payments under the Everest License Agreement, we have no committed external sources of funding. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us or at all. Funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies, clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations and other licensing arrangements. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Cash Flows

Discussion of our cash flow activities for the year ended December 31, 2021 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, 2022, filed with the SEC on March 14, 2023.

The following summarizes our cash flows for the periods indicated:

	Year Ended December 31,	
	2023	2022
(dollars in millions)		
Net cash used in operating activities	$ (81.6)	$ (58.8)
Net cash provided by (used in) investing activities	76.0	(91.4)
Net cash provided by financing activities	0.6	127.9
Effect of exchange rate changes on cash and cash equivalents	—	(0.1)
Net decrease in cash and cash equivalents	$ (5.0)	$ (22.4)

Cash Flows from Operating Activities

During the year ended December 31, 2023, cash used in operating activities was $81.6 million, which consisted of a net loss of $101.9 million and a net change of $4.7 million in our net operating assets and liabilities, and adjusted by non-cash charges of $15.5 million. The non-cash charges consisted of $18.1 million for stock-based compensation expense, $2.9 million for impairment loss of long-lived assets, $1.1 million for depreciation, and $0.2 million of non-cash interest expense, offset by $6.8 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 $4.9 million of other assets driven by the clinical activities related to PALIZADE clinical trial, a decrease of $0.3 million in operating lease asset and liabilities, offset by an increase of $6.3 million in accounts payable and accrued expenses due to timing of payments and increased clinical and manufacturing expenditures, and a decrease of $3.6 million in prepaid expenses and other current assets.

During the year ended December 31, 2022, cash used in operating activities was $58.8 million, which consisted of a net loss of $68.2 million and a net change of $4.5 million in our net operating assets and liabilities, and adjusted by non-cash charges of $13.8 million. The non-cash charges consisted of $14.0 million for stock-based compensation expense, $1.4 million of amortization of premium and discounts on marketable securities, $1.0 million for depreciation, and $0.2 million of non-cash interest expense. The change in our net operating assets and liabilities was primarily due to an increase of $5.8 million in prepaid expenses and other current assets driven by the start-up clinical activities related to PALIZADE and PORTOLA clinical trials, an increase of $0.4 million of other assets due to increased deposit from the lease modification for our headquarters, and a decrease of $0.1 million in operating lease asset and liabilities, offset by an increase of $1.8 million in accounts payable and accrued expenses due to timing of payments and increased clinical and manufacturing expenditures.

Cash Flows from Investing Activities

During the year ended December 31, 2023, net cash provided by investing activities was $76.0 million primarily relating to the maturities of marketable securities exceeding purchases of such marketable securities. Payments for the purchases of property and equipment was $1.8 million during the year ended December 31, 2023.

During the year ended December 31, 2022, net cash used in investing activities was $91.4 million primarily relating to the purchases of marketable securities exceeding maturities of such marketable securities. Payments for the purchases of property and equipment was $1.6 million during the year ended December 31, 2022.

Cash Flows from Financing Activities

During the year ended December 31, 2023, cash provided by financing activities was $0.6 million from the issuance of common stock pursuant to our employee equity plans.

During the year ended December 31, 2022, cash provided by financing activities was $127.9 million, consisting of $126.5 million of net proceeds received from the at-the-market offering program described above and $1.3 million from the issuance of common stock pursuant to our employee equity plans.

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 $201.4 million as of December 31, 2023, which consisted of bank deposits, highly liquid U.S. Treasury money market funds, U.S. Treasury securities, U.S. agency bonds, commercial paper and certificate of deposit. 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, 2023, our cash equivalents and marketable securities had a weighted average maturity of approximately six months and the longest maturity was 16 months. Due to the short-term duration and the lower risk profile of our cash equivalents and marketable securities, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities. We have the ability to hold our cash equivalents and marketable securities until maturity, and we therefore do not expect a change in market interest rates to affect our operating results or cash flows to any significant degree.

Approximately $0.7 million of our cash and marketable securities balance was located in Australia as of December 31, 2023. 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, 2023. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, 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, 2023 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, 2023.

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 the Company's Section 404(b) exemption based on Smaller Reporting Company status.

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.

Insider Trading Arrangements

During the fiscal quarter ended December 31, 2023, none of our directors or officers (as defined in Rule 16a-1(f)) adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Proposal 1: Election of Directors," "Executive Officers," "Information Regarding the Board and Corporate Governance" and "Delinquent Section 16(a) Reports," if applicable, in our 2024 Proxy Statement.

Information regarding our Code of Business Conduct and Ethics, or the Code of Conduct, required by this item will be contained in our 2024 Proxy Statement under the caption "Information Regarding the Board and Corporate Governance – Code of Business Conduct and Ethics," and is hereby incorporated by reference. If we make any substantive amendments to the Code of Conduct or grant any waiver from a provision of the Code of Conduct to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on its website. The full text of our Code of Conduct is available at the Investor Relations section of our website at *www.kezarlifesciences.com.* The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this Annual Report.

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 2024 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 2024 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 2024 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 Proposal 2 under the sections titled "Independent Registered Public Accounting Firm Fees" and "Pre-Approval Policies and Procedures" in our 2024 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

(a)(2) Financial Statement Schedules

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

(a)(3) Exhibits

Exhibit Number	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	Certificate of Amendment to the 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 16, 2023).
3.3	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*	Description of the Company's Securities.
4.3	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 Annual Report on Form 10-K (File No. 001-38542), filed with the Commission on March 17, 2022).
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+	2022 Inducement Plan (incorporated herein 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 August 11, 2022).
10.10+	Forms of Stock Option Grant Notice and Option Agreement under the 2022 Inducement Plan (incorporated herein 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 August 11, 2022).
10.11+	Non-Employee Director Compensation Policy.
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 Nick Mordwinkin, Ph.D., dated July 11, 2022 (incorporated herein 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 November 10, 2022).
10.14+	Advisor Agreement between the Company and Christopher Kirk, Ph.D., dated April 22, 2023 (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 August 10, 2023).
10.15+	Executive Employment Agreement, between the Company and Christopher J. Kirk, Ph.D., dated as of November 7, 2023 (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 November 13, 2023).
10.16+	Separation and Consulting Agreement, between the Company and John Fowler, dated October 3, 2023 (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 November 13, 2023).
10.17+	Separation Agreement, between the Company and Noreen Henig, M.D., dated October 23, 2023 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q (File No. 001-38542), filed with the Commission on November 13, 2023).
10.18†	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).
10.19†	Collaboration and License Agreement, by and between the Company and Everest Medicines II (HK) Limited, dated as of September 20, 2023 (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q (File No. 001-38542), filed with the Commission on November 13, 2023).
10.20	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).
10.21	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).
10.22	First Amendment to Lease, dated November 1, 2022, by and between the Company and GNS South Tower, LP (incorporated herein by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K (File No. 001-38542) filed with the Commission on March 14, 2023).
10.23	Loan and Security Agreement, dated as of November 4, 2021, by and between the Company and Oxford Finance LLC (incorporated herein by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K (File No. 001-38542), filed with the Commission on March 17, 2022).
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.
97.1	Incentive Compensation Recoupment Policy.
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 With Embedded Linkbase Documents.
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.

† Certain information has been omitted from this document in accordance with Regulation S-K, Item 601(b)(10).

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

Kezar Life Sciences, Inc.
(Registrant)

March 14, 2024

By: /s/ Christopher Kirk, Ph.D.
Christopher Kirk, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

March 14, 2024

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 Christopher Kirk, Ph.D. 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/ Christopher Kirk, Ph.D. **Christopher Kirk, Ph.D.**	Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2024
/s/ Marc Belsky **Marc Belsky**	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 14, 2024
/s/ Graham Cooper **Graham Cooper**	Chairman of the Board of Directors	March 14, 2024
/s/ Franklin Berger **Franklin Berger**	Director	March 14, 2024
/s/ John Fowler **John Fowler**	Director	March 14, 2024
/s/ Elizabeth Garner, M.D. **Elizabeth Garner, M.D.**	Director	March 14, 2024
/s/ Michael Kauffman, M.D., Ph.D. **Michael Kauffman, M.D., Ph.D.**	Director	March 14, 2024
/s/ Micki Klearman, M.D. **Micki Klearman, M.D.**	Director	March 14, 2024
/s/ Courtney Wallace **Courtney Wallace**	Director	March 14, 2024

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, 2023 and December 31, 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2023, 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, 2023 and December 31, 2022, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

Critical Audit Matter

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

Accounting for the Collaboration and License Agreement with Everest Medicines II (HK) Limited

As discussed in Note 10 to the consolidated financial statements, the Company entered into a Collaboration and License Agreement (the Everest License Agreement) with Everest Medicines II (HK) Limited (Everest). Under the terms of the Everest License Agreement, the Company granted to Everest an exclusive license to develop and commercialize one or more products containing the Company's proprietary compound, zetomipzomib in certain territories. During 2023, the Company received a one-time, irrecoverable, non-refundable, and non-creditable upfront payment of $7.0 million for the license and associated know-how of the Company's intellectual property.

The upfront payment was recognized as collaboration revenue when the performance obligation for the license and associated know-how was transferred to Everest.

We identified the assessment of the accounting for the Everest License Agreement as a critical audit matter. Subjective auditor judgment was required in evaluating the Company's identification of performance obligations because of the nature of the agreement.

The following are the primary procedures we performed to address this critical audit matter. We read the Everest License Agreement and evaluated the Company’s assessment of the accounting treatment, including the identification of the performance obligations. We inquired of personnel outside of the accounting function who were involved with the Everest License Agreement to corroborate management’s identification of the performance obligations.

/s/ KPMG LLP

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

San Francisco, California
March 14, 2024

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 35,493	$ 40,456
Marketable securities	165,879	236,105
Prepaid expenses and other current assets	5,578	9,161
Total current assets	206,950	285,722
Property and equipment, net	3,912	3,431
Operating lease right-of-use asset	4,778	9,741
Other assets	5,595	674
Total assets	$ 221,235	$ 299,568
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,251	$ 2,479
Accrued liabilities	6,481	5,953
Operating lease liabilities, current	3,012	2,565
Total current liabilities	17,744	10,997
Operating lease liabilities, noncurrent	5,852	8,865
Long-term debt	10,069	9,834
Total liabilities	33,665	29,696
Stockholders' equity:		
Common stock, $0.001 par value, 250,000,000 and 125,000,000 shares authorized as of December 31, 2023 and 2022, respectively; 72,779,077 and 68,493,429 shares issued and outstanding as of December 31, 2023 and 2022, respectively	73	68
Preferred stock, $0.001 par value, 10,000,000 shares authorized, zero shares issued and outstanding as of December 31, 2023 and 2022	—	—
Additional paid-in capital	538,390	519,620
Accumulated other comprehensive loss	(130)	(923)
Accumulated deficit	(350,763)	(248,893)
Total stockholders' equity	187,570	269,872
Total liabilities and stockholders' equity	$ 221,235	$ 299,568

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,		
	2023	**2022**	**2021**
Collaboration revenue	$ 7,000	$ —	$ —
Operating expenses:			
Research and development	85,697	51,009	38,935
General and administrative	26,540	20,153	15,724
Restructuring and impairment charges	6,187	—	—
Total operating expenses	118,424	71,162	54,659
Loss from operations	(111,424)	(71,162)	(54,659)
Interest income	11,104	4,108	188
Interest expense	(1,550)	(1,185)	(159)
Net loss	$ (101,870)	$ (68,239)	$ (54,630)
Net loss per common share, basic and diluted	$ (1.40)	$ (1.01)	$ (1.04)
Weighted-average shares used to compute net loss per common share, basic and diluted	72,553,645	67,368,935	52,759,335

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,		
	2023	2022	2021
Net loss	$ (101,870)	$ (68,239)	$ (54,630)
Other comprehensive income (loss), net of tax:			
Foreign currency translation adjustments	(2)	(49)	(50)
Net unrealized gain (loss) on marketable securities	795	(583)	(104)
Total other comprehensive income (loss), net of tax	793	(632)	(154)
Comprehensive loss	$ (101,077)	$ (68,871)	$ (54,784)

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

KEZAR LIFE SCIENCES, INC.
Consolidated Statements of Stockholders' Equity
(In thousands, except share and per share amounts)

	COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED OTHER COMPREHENSIVE	ACCUMULATED	TOTAL STOCKHOLDERS'
	SHARES	AMOUNTS	CAPITAL	INCOME (LOSS)	DEFICIT	EQUITY
Balance at December 31, 2020	46,359,743	$ 46	$ 267,093	$ (137)	$ (126,024)	$ 140,978
Issuance of common stock under the ATM Agreements, net of offering costs of $3,123	9,352,359	9	100,986	—	—	100,995
Issuance of common stock under employee stock incentive plans	547,645	1	2,069	—	—	2,070
Vesting related to shares of common stock issued pursuant to early exercises	—	—	21	—	—	21
Stock-based compensation expense	—	—	7,596	—	—	7,596
Other comprehensive loss	—	—	—	(154)	—	(154)
Net loss	—	—	—	—	(54,630)	(54,630)
Balance at December 31, 2021	56,259,747	$ 56	$ 377,765	$ (291)	$ (180,654)	$ 196,876
Issuance of common stock under the ATM Agreements, net of offering costs of $3,913	11,911,699	12	126,530	—	—	126,542
Issuance of common stock under employee stock incentive plans	321,983	—	1,319	—	—	1,319
Stock-based compensation expense	—	—	14,006	—	—	14,006
Other comprehensive loss	—	—	—	(632)	—	(632)
Net loss	—	—	—	—	(68,239)	(68,239)
Balance at December 31, 2022	68,493,429	$ 68	$ 519,620	$ (923)	$ (248,893)	$ 269,872
Cashless exercise of pre-funded warrants	3,792,876	4	(4)	—	—	—
Issuance of common stock under employee stock incentive plans	492,772	1	637	—	—	638
Stock-based compensation expense	—	—	18,137	—	—	18,137
Other comprehensive income	—	—	—	793	—	793
Net loss	—	—	—	—	(101,870)	(101,870)
Balance at December 31, 2023	72,779,077	$ 73	$ 538,390	$ (130)	$ (350,763)	$ 187,570

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,		
	2023	2022	2021
Cash flows from operating activities:			
Net loss	$ (101,870)	$ (68,239)	$ (54,630)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,066	1,023	1,510
Stock-based compensation	18,137	14,006	7,596
Amortization of premiums and discounts on marketable securities	(6,830)	(1,401)	1,770
Amortization of debt discount and issuance costs and other non-cash interest	235	212	91
Impairment loss of property and equipment	208	—	—
Impairment loss of right-of-use asset	2,700	—	—
Other	3	12	—
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	3,583	(5,787)	1,051
Other assets	(4,921)	(392)	—
Accounts payable and accrued liabilities	6,347	1,814	1,217
Operating lease asset and liabilities	(303)	(94)	(1,042)
Net cash used in operating activities	(81,645)	(58,846)	(42,437)
Cash flows from investing activities:			
Purchases of property and equipment	(1,810)	(1,578)	(316)
Purchases of marketable securities	(180,399)	(332,203)	(156,378)
Maturities of marketable securities	258,250	242,389	128,250
Proceeds from sale of equipment	5	—	—
Net cash provided by (used in) investing activities	76,046	(91,392)	(28,444)
Cash flows from financing activities:			
Proceeds from issuance of common stock under at-the-market offerings and warrants, net of issuance costs	—	126,542	100,970
Proceeds from long-term debt, net of debt discount and issuance costs of $469	—	—	9,531
Proceeds from issuance of common stock under employee stock incentive plans	638	1,319	2,084
Net cash provided by financing activities	638	127,861	112,585
Effect of exchange rate changes on cash and cash equivalents	(2)	(49)	(50)
Net (decrease) increase in cash and cash equivalents	(4,963)	(22,426)	41,654
Cash and cash equivalents at the beginning of period	40,456	62,882	21,228
Cash and cash equivalents at the end of period	$ 35,493	$ 40,456	$ 62,882
Supplemental disclosures of noncash investing and financing information:			
Reclassification of employee stock liability to equity upon vesting	$ —	$ —	$ 21
Purchase of property and equipment in accounts payable	$ —	$ 47	$ 442
Par value of common stock upon cashless exercise of prefunded warrants	$ 4	$ —	$ —
Supplemental disclosures			
Cash paid for interest	$ 1,315	$ 973	$ 69

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, developing novel small molecule therapeutics to treat unmet needs in immune-mediated diseases and cancer. The Company's principal operations are in South San Francisco, California, and it operates in one segment.

Liquidity

Since commencing operations in mid-2015, substantially all of the Company's efforts have been focused on research, development and the advancement of the Company's lead product candidates, zetomipzomib and KZR-261. The Company's ultimate success depends on the outcome of the ongoing research and development activities. The Company has not yet generated product sales and as a result has experienced operating losses since inception and had an accumulated deficit of $350.8 million as of December 31, 2023. 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 such as Everest Collaboration that was entered into on September 20, 2023. 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, 2023 will be sufficient to fund the Company's cash requirements for at least 12 months following the issuance of these financial statements.

In 2022, the Company sold an aggregate of 11,911,699 shares of its common stock at a weighted average purchase price of $10.95 per share pursuant to the Company's at-the-market offering program for net proceeds of approximately $126.5 million after deducting $3.9 million in commissions paid.

In 2021, the Company sold an aggregate of 9,352,359 shares of its common stock at a weighted average purchase price of $11.13 per share pursuant to the Company's at-the-market offering program for net proceeds of approximately $101.0 million after deducting $3.1 million in commissions paid.

In November 2021, the Company entered into a loan and security agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford Finance"), which provided the Company up to $50.0 million in borrowing capacity across five potential tranches. The initial tranche of $10.0 million was funded at the closing of the Loan Agreement. The remaining tranches were dependent on achieving certain clinical trial milestones. The Company declined these remaining tranches in borrowing capacity available to it under the Loan Agreement.

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 revenue and expenses during the reporting period. Significant items subject to such judgments, estimates and assumptions include the valuation of marketable securities, impairment of long-lived assets, determining the fair-value of stock-based compensation, and

evaluating the progress to completion of external 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.

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.

Foreign Currency Translation

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

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents are stated at fair value. The Company has no restricted cash.

Marketable Securities

All marketable securities have been classified as "available-for-sale" and are carried at estimated fair value, based upon quoted market prices or pricing models for similar securities. The Company considers its available-for-sale portfolio as available for use in current operations. Accordingly, those marketable securities with contractual maturities greater than one year from the date of purchase are classified as current assets on the accompanying balance sheets.

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. Realized gains and 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 each of its investments in available-for sale debt securities whose fair value is below its cost basis to determine if the investment's impairment due to credit-related factors or noncredit-related factors. 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-related loss does exist for available-for-sale debt securities and should be recognized, an allowance for credit losses will be recorded in other income (expense), net. The portion of the impairment that is not credit-related is recorded as a reduction of other comprehensive income or loss, net of applicable taxes. 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, 2023, the majority of the Company's cash, cash equivalents and marketable securities were held by financial institutions in the United States,

while approximately $0.7 million was held by a financial institution in Australia. Such deposits in the United States were in excess of insured limits.

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 the non-current portion of advance deposits for the clinical related costs and security deposits for the Company's operating leases of office and laboratory space.

Leases

The Company determines if an arrangement contains a lease at inception of the contract and determines the classification of its leases at lease commencement. At lease commencement, the Company records a lease liability based on the present value of future lease payments over the expected lease term. The lease term used may include options to extend the lease when it is reasonably certain that the Company will exercise the option. 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 over a similar term, an amount equal to the lease payments in a similar economic environment. The Company records a corresponding right-of-use ("ROU") 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 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.

ROU asset and operating lease liabilities are remeasured upon reassessment events and modifications to leases using the present value of remaining lease payments and estimated incremental borrowing rate at the time of remeasurement, as applicable.

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

Impairment of Long-Lived Assets

Long-lived assets include property and equipment and ROU asset. 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 fully recoverable. An estimate of undiscounted future cash flows generated by the long-lived asset, or appropriate group of assets, is compared to the carrying value to determine whether an impairment exists at its lowest level of identifiable cash flows. Impairment loss is measured based on the difference between the asset's fair value and its carrying value. An estimate of the asset's fair value is based on quoted market prices in active markets, if available. If quoted market prices are not available, the estimate of fair value is based on various valuation techniques using unobservable fair value inputs, such as a projected discounted future cash flows. 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. In December 2023, the Company wrote down the long-lived assets to their estimated fair values and recognized the impairment loss in the Consolidated Statement of Operations (see Note 3, 5, 6 and 17).

Debt Issuance Costs and Debt Discounts

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

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. The Company applies the following five-step revenue recognition model in accordance with ASC Topic 606, *Revenue from Contracts with Customers (ASC 606)* in order to determine revenue:

(i) identify the contract with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the Company satisfies a performance obligation.

At contract inception, the Company identifies the goods or services promised within the contract and assesses whether each promised good or service is distinct for the purpose of identifying performance obligations. A good or service that is promised to a customer is distinct if (1) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer; and (2) the Company's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. In assessing whether a promised good or service is distinct in the context of a collaboration or licensing arrangement, the Company considers factors such as the research, manufacturing and commercialization capabilities of a collaboration partner and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and, if so, they are considered performance obligations.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their stand-alone selling prices ("SSP") on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is limited to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time. If over time, recognition is based on the use of either an output or an input method, such that the method used best depicts the transfer of control to the customer.

The Company recognizes as an asset the incremental costs of obtaining a contract with a customer if the costs are expected to be recovered. As a practical expedient, the Company recognizes the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset that it otherwise would have recognized is one year or less.

Research and Development Costs

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

The Company records 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. The Company determines the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with our internal personnel and external service providers as to the progress or stage of completion of trials or services for the services when we have not yet been invoiced or notified of the actual progress and cost. Any payments made in advance of services provided are recorded as prepaid assets, which are expensed as the contracted services are performed. As actual costs become known, we adjust our accrued estimates. Although the Company do not expect its 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 its estimates and could result in us reporting amounts that are too high or too low in any particular period.

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.

Income Taxes

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

The Company records a valuation allowance against deferred tax assets if it is more likely than not that a portion or all of the asset will not be realized in future periods. In making such determination, the Company considers all

available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations.

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

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock and pre-funded warrants outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is the same as basic net loss per share for the periods presented since the effects of potentially dilutive securities are antidilutive given the net loss of the Company. The pre-funded warrants are included in the computation of basic and diluted net loss per common share as the exercise price is negligible and the pre-funded warrants are fully vested and exercisable. Common share equivalents are only included in the calculation of diluted net loss per common share when their effect is dilutive.

Recently Issued Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2023-09 *Income Taxes (Topic 740) – Improvements to Income Tax Disclosures* ("ASU 2023-09"), which requires entities to disclose specific categories in the income tax rate reconciliation annually and provide additional information for reconciling items that meet a qualitative threshold. ASU 2023-09 also requires that entities disclose annually additional information about income taxes paid and disaggregated information for certain items. ASU 2023-09 is effective for the Company beginning on January 1, 2025. The Company is currently evaluating the impact of the adoption of ASU 2023-09 on its financial position, results of operations and cash flows.

In November 2023, the FASB issued Accounting Standards Update No. 2023-07 *Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which requires entities to disclose incremental segment information on an annual and interim basis. ASU 2023-07 requires entities with a single reportable segment to provide all the disclosures required by the amendments in ASU 2023-07 and all existing segment disclosures in *Segment Reporting (Topic 280)*. ASU 2023-07 is effective for the Company beginning on January 1, 2024, and interim periods beginning on January 1, 2025. The Company does not expect the adoption of ASU 2023-07 to have a material impact on its financial position, results of operations or cash flows.

In March 2020, the FASB issued Accounting Standards Update No. 2020-04 *Reference Rate Reform (Topic 848) – Facilitation of the Effects of Reference Rate Reform on Financial Reporting* ("ASU 2020-04"), which provides temporary optional expedients and exceptions to accounting guidance on contract modifications and hedge accounting to ease entities' financial reporting burdens as the market transitions from the London Interbank Offered Rate ("LIBOR") and other interbank offered rates to alternative reference rates. This guidance generally allows for contract modifications solely related to the replacement of the reference rate to be accounted for as a continuation of the existing contract instead of as an extinguishment of the contract, without triggering certain accounting impacts that could be required associated with an extinguishment of the contract. In January 2021, the FASB issued Accounting Standards Update No. 2021-01 *Reference Rate Reform (Topic 848) – Scope* ("ASU 2021-01"), to expand the scope of this guidance to include derivatives. In December 2022, the FASB issued Accounting Standards Update No. 2022-06 *Reference Rate Reform (Topic 848) – Deferral of the Sunset Date of Topic 848* ("ASU 2022-06"), which extends the period of time entities can utilize the reference rate reform relief guidance under ASU 2020-04 from December 31, 2022 to December 31, 2024. As discussed in Note 7 of the consolidated financial statements, in June 2023 the Company's Loan Agreement was amended and effective July 1, 2023, the interest base transitioned from LIBOR to Secured Overnight Financing Rate ("SOFR"). The Company applied the above guidance when accounting for this change, and adoption of this guidance did not have a material impact on our financial statements.

As of December 31, 2023, the Company have no debt instruments that use LIBOR as a reference rate, and this guidance is not expected to have a material impact on its financial statements in the future.

3. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. The carrying amount of certain financial instruments, including cash, cash equivalents, 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 financial assets or liabilities measured using Level 3 inputs as of December 31, 2023 or 2022.

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, 2023			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Cash equivalents:				
U.S. Treasury money market funds	$ 35,349	$ 35,349	$ —	$ —
Marketable securities:				
Certificate of deposit	544	—	544	—
U.S. Treasury securities	54,175	54,175	—	—
Commercial paper	65,070	—	65,070	—
U.S. Government agency bonds	46,090	—	46,090	—
Total	$ 201,228	$ 89,524	$ 111,704	$ —

	December 31, 2022			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Cash equivalents:				
U.S. Treasury money market funds	$ 38,745	$ 38,745	$ —	$ —
Marketable securities:				
U.S. Treasury securities	40,141	40,141	—	—
Commercial paper	117,478	—	117,478	—
Corporate debt securities	1,978	—	1,978	—
U.S. Government agency bonds	76,508	—	76,508	—
Total	$ 274,850	$ 78,886	$ 195,964	$ —

Nonrecurring Fair Value Measurements

ROU asset associated with Suite 400 of the Company's headquarters in South San Francisco, California, is a separate asset group measured at fair value on a nonrecurring basis at December 31, 2023 due to an impairment recognized on the ROU asset at that date (see Note 6). Fair value of this asset group calculated as the present value of the estimated future cash flows of sublease income attributable to the ROU asset associated with Suite 400, was classified in Level 3 of the fair value hierarchy. When calculating the present value of the estimated future cash flows, sublease income was estimated to increase at a rate of 3.5% per year, and the cash flows were discounted using a rate of 13.3%.

4. Available-for-Sale Securities

The following table is a summary of available-for-sale securities recorded in cash and cash equivalents or marketable securities in the Company’s consolidated balance sheets as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:				
U.S. Treasury money market funds	$ 35,349	$ —	$ —	$ 35,349
Marketable securities:				
Certificate of deposit	544	—	—	544
U.S. Treasury securities	54,066	151	(42)	54,175
Commercial paper	65,038	41	(9)	65,070
U.S. Government agency bonds	46,115	27	(52)	46,090
Total	$ 201,112	$ 219	$ (103)	$ 201,228
Cash				144
Total cash, cash equivalent and marketable securities				$ 201,372

	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:				
U.S. Treasury money market funds	$ 38,745	$ —	$ —	$ 38,745
Marketable securities:				
U.S. Treasury securities	40,340	—	(199)	40,141
Commercial paper	117,855	2	(379)	117,478
Corporate debt securities	1,978	—	—	1,978
U.S. Government agency bonds	76,610	56	(158)	76,508
Total	$ 275,528	$ 58	$ (736)	$ 274,850
Cash				1,711
Total cash, cash equivalent and marketable securities				$ 276,561

The Company has not recognized an allowance for credit losses on any securities in an unrealized loss position as of December 31, 2023 and 2022.

The following tables display 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, 2023 and 2022 (in thousands):

	December 31, 2023			
	Less than 12 months		12 months or greater	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. Treasury securities	$ 16,261	$ (42)	$ —	$ —
Commercial paper	20,789	(9)	—	—
U.S. Government agency bonds	39,052	(52)	—	—
Total	$ 76,102	$ (103)	$ —	$ —

	December 31, 2022			
	Less than 12 months		12 months or greater	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. Treasury securities	$ 33,782	$ (196)	$ 6,359	$ (3)
Commercial paper	112,706	(379)	—	—
Corporate debt securities	1,978	—	—	—
U.S. Government agency bonds	33,942	(147)	5,490	(11)
Total	$ 182,408	$ (722)	$ 11,849	$ (14)

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.

The Company currently does not intend to sell these securities prior to maturity, and it is not more likely than not that the Company will be required to sell these securities before recovery of their amortized cost basis, which may be at maturity. The Company evaluated securities with unrealized losses to determine whether such losses, if any, were due to credit-related factors and determined that there were no credit-related losses to be recognized as of December 31, 2023. There were no sales of available-for-sale securities in any of the periods presented.

As of December 31, 2023, 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	$ 186,428	$ 186,477
One to two years	14,684	14,751
Total available-for-sale securities	$ 201,112	$ 201,228

5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of December 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022
Advance for clinical-related costs, current	$ 1,818	$ 6,760
Licenses, dues and subscriptions	506	376
Insurance	712	741
Receivable from Everest (Note 10)	1,596	—
Interest receivable	695	774
Others	251	510
Total prepaid expenses and other current assets	$ 5,578	$ 9,161

Property and Equipment, Net

Property and equipment, net consisted of the following as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022
Leasehold improvements	$ 3,488	$ 3,366
Furniture, laboratory and office equipment	5,559	4,423
Computer equipment	285	244
Total property and equipment	9,332	8,033
Less: accumulated depreciation and amortization	(5,420)	(4,602)
Property and equipment, net	$ 3,912	$ 3,431

Depreciation expense was $1.1 million, $1.0 million, and $0.9 million for the year ended December 31, 2023, 2022, and 2021, respectively. In December 2023, the Company identified certain property and equipment, namely leasehold improvements, computer equipment, office furniture and fixtures that no longer utilized under current or expected future operations (see Note 17). Accordingly, the Company recognized impairment loss of $0.2 million within restructuring and impairment charges on the Company's Consolidated Statement of Operations for the year ended December 31, 2023.

Other Assets

Other assets consisted of the following as of December 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022
Advance for clinical related costs, non-current	$ 4,787	$ —
Deposits for operating lease	674	674
Others	134	—
Total other assets	$ 5,595	$ 674

Accrued Liabilities

Accrued liabilities consisted of the following as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022
Accrued preclinical and research costs	$ 756	$ 1,368
Accrued clinical costs	1,801	1,007
Accrued employee-related costs	3,708	3,260
Accrued professional services	110	53
Other	106	265
Total accrued liabilities	$ 6,481	$ 5,953

6. Lease

In November 2022, the Company entered into an amendment to the lease agreement for its corporate headquarters in South San Francisco, California, which expanded the leased premises to include Suite 400 in the same building as its corporate headquarters and extending the lease term of the original premises to be coterminous with the expansion premises to July 31, 2026. The transaction was treated as a lease modification as of the effective date and resulted in the recognition of approximately $8.0 million in new lease liabilities and right-of-use assets.

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

As of December 31, 2023, the weighted average remaining lease term was 2.58 years and the weighted average discount rate used to determine the operating lease liability was 11.67%.

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

	For the Year Ended December 31, 2023	2022	2021
Cash paid for operating lease liabilities	$ 2,566	$ 1,032	$ 1,042
Operating lease costs	3,464	1,493	1,099
Variable lease costs	1,502	807	765

Maturities of lease liabilities as of December 31, 2023 were as follows:	
Less than 12 months	$ 3,890
13 - 24 months	4,025
25 - 36 months	2,418
Total undiscounted lease payments	10,333
Less: imputed interest	(1,469)
Total lease liabilities	$ 8,864
Operating lease liabilities, current	3,012
Operating lease liabilities, noncurrent	5,852
Total operating lease liabilities	$ 8,864

For the years ended December 31, 2023, 2022 and 2021, the Company recognized $3.5 million, $1.5 million and $1.1 million of rent expense, respectively. Variable lease costs were $1.5 million, $0.8 million and $0.8 million for the years ended December 31, 2023, 2022 and 2021, respectively.

In December 2023, the Company committed to a plan to sublease Suite 400 of its corporate headquarters following the Workforce Reduction (see Note 17) and evaluated the recoverability of ROU asset by comparing the carrying amount of the asset to future net undiscounted cash flows associated with the asset. The ROU asset is considered to be impaired as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Consequently, the Company recognized $2.7 million impairment charge in 2023.

7. Long-Term Debt

In November 2021, the Company entered into the Loan Agreement with Oxford Finance, which provides the Company up to $50.0 million in borrowing capacity across five potential tranches (each a "Term Loan," and collectively "Term Loans"). The initial tranche of $10.0 million was funded at the closing of the Loan Agreement. The remaining tranches were dependent on achieving certain clinical trial milestones. The Company declined these remaining tranches in borrowing capacity available to it under the Loan Agreement. The loan facility is secured by all assets except intellectual property, which has a negative pledge, and will mature on November 1, 2026 (the "Maturity Date"). There are no warrants or financial covenants associated with the Loan Agreement.

Until June 30, 2023, the Term Loans bore interest at a floating per annum rate (based on the actual number of days elapsed divided by a year of 360 days) equal to the sum of (a) the greater of (i) 30-day U.S. LIBOR rate reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue and (ii) 0.08%, plus (b) 7.87%. The Company is required to make monthly interest-only payments prior to the amortization date of January 1, 2025, subject to a potential one-year extension upon satisfaction of certain conditions. A LIBOR transition event occurred effective July 1, 2023 and Oxford Finance subsequently replaced the LIBOR rate with the 1-month CME term SOFR plus 0.1%. The rate change did not require contract remeasurement at the effective date of the change or a reassessment of any previous accounting determinations pertaining to the facility. The rate change did not have a material impact on the Company's financial statements.

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

The Loan Agreement also includes subjective acceleration clauses which permit the lenders to accelerate the Maturity Date under certain circumstances, including, but not limited to, material adverse effects on a Company's financial status or otherwise. As of December 31, 2023, the Company is in compliance with all covenants in Agreement.

Interest expense was $1.6 million and $1.2 million for the year ended December 31, 2023 and 2022, respectively. The initial effective interest rate on the Term Loans, including the amortization of the debt discount and issuance costs, and accretion of the final payment, was 11%. The components of the long-term debt balance are as follows:

	December 31, 2023	December 31, 2022
Principal loan balance	$ 10,000	$ 10,000
Unamortized debt discount and issuance costs	(243)	(342)
Cumulative accretion of final fee	312	176
Long-term debt, net	$ 10,069	$ 9,834

As of December 31, 2023, the estimated future principal payments due were as follows:

Years Ending December 31,	
2024	$ —
2025	5,217
2026	4,783
Total	$ 10,000

8. Pre-Funded Warrants

In connection with the Company's previous underwritten public offerings, the Company issued pre-funded warrants to purchase an aggregate of 3,793,706 shares of the Company's common stock. Each pre-funded warrant entitled the holder to purchase shares of common stock at an exercise price of $0.001 per share and expired 20 years from the date of issuance. These warrants were recorded as a component of stockholders' equity within additional paid-in capital. In January 2023, warrant holders exercised 2,236,553 shares of outstanding pre-funded warrants, and in April 2023, warrant holders exercised the remaining 1,557,153 shares of outstanding pre-funded warrants. As of December 31, 2023, there were no pre-funded warrants outstanding.

9. Stock-Based Compensation

Stock Incentive Plans

2022 Inducement Plan

In April 2022, the Company adopted the Kezar Life Sciences, Inc. 2022 Inducement Plan (the "Inducement Plan"), which is a non-stockholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq Listing Rule 5635(c)(4), for the award of nonstatutory stock options ("NSOs"), restricted stock units ("RSUs") and other equity awards as permitted by the Inducement Plan (collectively, "Inducement Awards") to persons not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to such persons entering into employment with the Company ("Eligible Recipients"). Under the Inducement Plan, the Company may grant up to 3,000,000 shares of Common Stock in the form of Inducement Awards to Eligible Recipients in compliance with the requirements of Nasdaq Listing Rule 5635(c)(4). Awards must be approved by either a majority of the Company's independent directors or the Company's independent compensation committee. Consultants and directors are not eligible to received grants under the Inducement Plan.

As of December 31, 2023, options to purchase 1,221,574 shares of common stock were outstanding and 1,778,426 shares were available for future issuance under the Inducement Plan.

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"), 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"), NSOs, stock appreciation rights, restricted stock awards, RSUs and other stock-based awards. As of December 31, 2023, options to purchase 10,501,285 shares of common stock and 219,609 RSUs were outstanding, and 1,312,857 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 allowed for early exercise of certain options prior to vesting. Upon termination of employment, the unvested shares were subject to repurchase at the original exercise price. As of December 31, 2023, options to purchase 1,387,858 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"). 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, 2023, 589,950 shares of common stock had been issued under the ESPP and 743,274 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, 2023.

Option Repricing

On July 24, 2023, the Compensation Committee of the Company's board of directors approved a stock option repricing (the "Option Repricing") in which the exercise price of certain outstanding options to purchase shares of the Company's common stock under the 2018 Plan was reduced to $2.28 per share, the closing price of the Common Stock on July 24, 2023. Outstanding options that were granted under the 2015 Plan and the Inducement Plan were not included in the Option Repricing. The Option Repricing included options granted pursuant to the 2018 Plan that were held by, among others, members of the Company's board of the directors (other than options granted in June 2023) and the Company's named executive officers and principal financial officer.

As a result of the Option Repricing, 9,904,755 shares of vested and unvested stock options outstanding as of July 24, 2023, with original exercise prices ranging from $2.44 to $22.85 per share, were repriced to $2.28 per share. The total incremental fair value to be recognized as a result of the repricing was approximately $4.7 million. The incremental fair value attributable to the vested option shares on the date of Option Repricing, totaling approximately $2.3 million, was recognized as stock-based compensation expense in 2023. The remaining incremental fair value attributable to the unvested option shares will be amortized over the remaining requisite service periods, which range from the date of the Option Repricing through the end of 2026.

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, 2022	9,684,810	$ 8.12	7.6	$ 15,407
Options granted	5,808,994	$ 4.56		
Options exercised	(155,871)	$ 1.65		$ 376
Options cancelled/forfeited	(2,227,216)	$ 5.26		
Outstanding at December 31, 2023	13,110,717	$ 2.60	7.1	$ 118
Vested and exercisable at December 31, 2023	7,093,081	$ 2.66	5.6	$ 10

The weighted average grant date fair value of options granted during the years ended December 31, 2023 and 2022 was $3.43 and $9.81 per share, respectively. The aggregate intrinsic value of exercised stock options during the years ended December 31, 2023 and 2022 was $0.4 million and $1.5 million, respectively. The aggregate intrinsic value is calculated as the difference between the exercise price and the estimated fair value of the Company's common stock at the date of exercise.

Restricted Stock Units Activity

During the 12 months ended December 31, 2023, the Company granted RSUs to certain employees pursuant to the 2018 Plan. One-third of each RSU grant will vest annually following the vesting commencement dates, over a vesting period of 3 years. RSUs are awards that entitle the holder to receive freely tradable shares of the Company's common stock upon vesting and are not forfeitable once fully vested. The valuations for these RSUs were based on the closing prices of the Company's common stock on the grant dates and recognized as stock-based compensation expense over the respective vesting terms.

	Number of RSUs Outstanding	Weighted Average Grant-Date Fair Price
Outstanding as of December 31, 2022	434,790	$ 9.80
RSUs granted	81,619	$ 6.84
RSUs vested	(125,188)	$ 9.88
RSUs forfeited	(171,612)	$ 9.10
Outstanding as of December 31, 2023	219,609	$ 9.20

Stock-Based Compensation Expense

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

	Year Ended December 31,		
	2023	2022	2021
Research and development	$ 8,612	$ 6,612	$ 2,955
General and administrative	9,525	7,394	4,641
Total stock-based compensation expense	$ 18,137	$ 14,006	$ 7,596

As of December 31, 2023, the unrecognized stock-based compensation cost was $28.8 million with an estimated weighted average amortization period of 2.6 years.

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

	Options			ESPP Rights		
	Year Ended December 31,			Year Ended December 31,		
	2023	2022	2021	2023	2022	2021
Expected term (years)	5.5 - 6.1	5.5 - 6.1	5.5 - 6.1	0.5	0.5	0.5
Expected volatility	87.6 - 88.4%	84.3 - 88.5%	85.4 - 88.1%	74.4 - 91.2%	85.6 - 114.9%	64.0 - 77.2%
Risk-free interest rate	3.5 - 4.7%	1.6 - 4.1%	0.5 - 1.3%	5.3 - 5.4%	1.5 - 4.5%	0.0 - 0.1%
Expected dividend yield	—	—	—	—	—	—

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

10. Everest Collaboration

On September 20, 2023, the Company entered into a Collaboration and License Agreement (the “Everest License Agreement”) with Everest Medicines II (HK) Limited (“Everest”) pursuant to which, among other things, the Company granted to Everest an exclusive license to develop and commercialize one or more products containing the Company’s proprietary compound, zetomipzomib (the “Products”), in the licensed field in the Greater China region (Mainland China, Taiwan, Hong Kong and Macau), South Korea, Singapore, Malaysia, Thailand, Indonesia, Vietnam and the Philippines (the “Territory”). The licensed field includes all uses other than the diagnosis or treatment in humans of cancerous or pre-cancerous diseases or conditions. During the PALIZADE trial, Everest will contribute their local regulatory and clinical trial expertise and will be responsible for study costs in the Territory. Everest Medicines Limited is also a party to the Everest License Agreement solely for limited purposes, including to guarantee the performance by Everest of its obligations under the Everest License Agreement.

Under the terms of the Everest License Agreement, the Company received one-time, irrecoverable, non-refundable and non-creditable upfront payment of $7.0 million in October 2023, certain variable payments for manufacturing supply services, and is entitled to receive milestone payments upon achievement of certain development, regulatory and commercial milestone events, for total potential milestone payments of up to $125.5 million. In addition, Everest will pay to the Company tiered royalties on the net sales of the Products in the Territory during the term of the Everest License Agreement ranging from the single digit to the low-teens, subject to certain reductions for patent expiration, generic competition and payments for licenses to third-party patents.

The term of the Everest License Agreement will continue on a market-by-market basis until expiration of the relevant royalty term of the Products, unless terminated earlier. Everest has the right to terminate the Everest License Agreement for convenience following completion, suspension or termination of the PALIZADE clinical trial. The Company may terminate the Everest License Agreement if Everest challenges the Company’s patents or fails to perform any development or commercialization activities for a continuous period of more than twelve (12) months, subject to certain exceptions. In addition, either party may terminate the Everest License Agreement for the other party’s uncured breach or insolvency, and the Everest License Agreement will automatically terminate in the event of termination of the Company’s exclusive license agreement with Onyx Therapeutics, Inc.

Under the terms of the Everest License Agreement, at the election of Everest, the Company may manufacture and provide clinical supply to Everest to use in development and commercialization in the Territory at the fully burdened manufacturing cost plus specified margins, as defined within the Everest License Agreement. Certain of these provisions were determined to be options to acquire additional goods or services at a price that approximates the

stand-alone selling price for that good or service and therefore do not represent material rights, or separate performance obligations, within the context of the Everest License Agreement. The Company evaluated the Everest License Agreement and determined it was within the scope of ASC 606. The transaction price was determined to consist of the upfront payment of $7.0 million.

License of Intellectual Property. The license to the Company's intellectual property and associated know-how represents a distinct performance obligation. The license and associated know-how was transferred to Everest in the third quarter of 2023 to satisfy this performance obligation. The Company allocated the full transaction price to the license of the Company's intellectual property and accordingly recognized collaboration revenue of $7.0 million during the year ended December 31, 2023.

Milestone Payments. The potential development, regulatory and commercial milestone payments are paid upon achievement of certain milestones as defined in the Everest License Agreement. It was determined that their achievement is highly dependent on factors outside of the Company's control. These payments have been fully constrained until the Company concludes that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods and, as such, have been excluded from the transaction price. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of each milestone and any related constraint and, if necessary, adjust its estimate of the overall transaction price. As of December 31, 2023, the Company has not recognized any revenue associated with development, regulatory and commercial milestones.

Royalties. Any consideration related to royalties will be recognized if and when the related sales occur, as they were determined to relate predominantly to the license granted to Everest and, therefore, have also been excluded from the transaction price. No royalty revenue was recognized as of December 31, 2023.

As of December 31, 2023, the Company had a receivable of $1.6 million, representing the billed amount related to Everest's share of the Territory-specific direct costs and pro rata portion of indirect costs incurred to conduct PALIZADE study under the Everest License Agreement for the three months ended December 31, 2023. The receivable amount was recognized as contra research and development expense and included in prepaid expenses and other current assets in the Company's Consolidated Balance Sheet.

11. 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 Delaware corporate law. The Company currently has directors' and officers' insurance.

12. 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 paid $5.0 million in milestone payments under the Onyx License Agreement in 2023, and may be required to make future payments of up to $167.5 million upon achievement of certain development and commercial milestones for zetomipzomib, as well as royalty payments in the mid to high single digits on future annual net sales, if any.

13. 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, 2023, 2022 and 2021, the Company recorded matching contributions of approximately $0.8 million, $0.6 million and $0.4 million, respectively.

14. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2023, 2022 and 2021. 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.

In March 2020, the Coronavirus Aid, Relief and Economic Security ("CARES") Act was signed into law. The CARES Act included several tax changes as part of its economic package. These changes principally related to expanded net operating loss carryback periods, increases to interest deductibility limitations, and accelerated alternative minimum tax refunds. The CARES Act enacted the Employee Retention Credit ("ERC") to incentivize companies to retain employees, which was subsequently modified by extension of the CARES Act. Under the provisions of the CARES Act and its subsequent extension, the Company was eligible for ERCs, subject to certain criteria. During the year ended December 31, 2023, the Company received refunds of approximately $1.4 million related to ERCs that offset the related payroll expenses in the respective operating costs and expenses line item in the Consolidated Statement of Operations.

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

	Year Ended December 31,		
	2023	2022	2021
Domestic	$ (101,613)	$ (68,097)	$ (54,581)
Foreign	(257)	(142)	(49)
Total	$ (101,870)	$ (68,239)	$ (54,630)

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 $0, $79,000 and $325,000 of R&D tax credits as a reduction of payroll expenses to offset its payroll tax liabilities for the years ended December 31, 2023, 2022 and 2021, respectively.

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

	Year Ended December 31,		
	2023	2022	2021
Federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State taxes, net of federal benefit	3.0	1.3	1.3
Foreign tax rate differential	0.0	0.0	0.0
Permanent differences	(2.1)	(0.6)	(2.2)
Research and development credit	3.2	2.5	4.0
Change in valuation allowance	(25.1)	(24.2)	(24.1)
Provision for income taxes	— %	— %	— %

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

	Year Ended December 31,	
	2023	2022
Deferred tax assets		
Reserves and accruals	$ 4,692	$ 3,420
Net operating loss carryforwards	42,984	37,939
Research and development credit carryforwards	12,032	7,603
Lease Liabilities	1,862	2,402
R&D Capitalization	22,248	7,979
Gross deferred tax assets	83,818	59,343
Valuation allowance	(82,541)	(56,983)
Net deferred tax assets	1,277	2,360
Deferred tax liabilities		
Property and equipment	(273)	(313)
Right-of-use asset	(1,004)	(2,047)
Net deferred tax assets	$ —	$ —

Effective January 1, 2022, under the Tax Cuts and Jobs Act, for tax purposes the Company is required to capitalize and subsequently amortize all R&D expenditures over five years for research activities conducted in the U.S. and over fifteen years for research activities conducted outside of the U.S. The Company generates a deferred tax asset for capitalized R&D expenditures for the year ended December 31, 2023 which is fully offset with a valuation allowance.

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, 2023, and December 31, 2022 have been fully offset by a valuation allowance. The valuation allowance increased approximately $25.6 million, $15.2 million and $12.4 million during the years ended December 31, 2023, 2022, and 2021, respectively.

As of December 31, 2023, the Company had federal net operating loss ("NOL") carryforward of $187.1 million and a federal research and development tax credit carryforward of $11.8 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 $165.0 million generated from years ended after December 31, 2017, carryforward indefinitely. As of December 31, 2023 the Company had a state NOL carryforward of $44.4 million, which will expire beginning in 2035, and a state research and development tax credit carryforward of $5.2 million, which does not expire.

As of December 31, 2023, the Company also had accumulated Australian tax losses of $2.0 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, 2023. 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 $4.1 million of unrecognized tax benefits as of December 31, 2023. No liability related to uncertain tax positions is recorded on the financial statements. All uncertain tax positions are currently recorded as a reduction to the Company's deferred tax assets, which are subject to a valuation allowance. If recognized, none of the unrecognized tax benefits would affect the effective tax rate. The Company does not anticipate that the total

amounts of unrecognized tax benefits will significantly increase or decrease in the next 12 months. The Company's policy is to include interest and penalties related to unrecognized tax benefits within the provision for income taxes, as necessary. The Company did not recognize any accrued interest and penalties related to gross unrecognized tax benefits related to the year ended December 31, 2023. A reconciliation of the Company's unrecognized tax benefits for the year ended December 31, 2023, 2022 and 2021 is as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Balance at the beginning of the year	$ 2,522	$ 1,643
Decrease related to prior year tax positions	(222)	(187)
Increase related to current year tax positions	1,774	1,066
Balance at the end of the year	$ 4,074	$ 2,522

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.

15. 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,		
	2023	2022	2021
Numerator:			
Net loss	$ (101,870)	$ (68,239)	$ (54,630)
Denominator:			
Weighted-average shares of common stock outstanding	72,553,645	67,368,935	52,759,335
Net loss per share, basic and diluted	$ (1.40)	$ (1.01)	$ (1.04)

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,		
	2023	2022	2021
Options to purchase common stock	13,110,717	9,684,810	6,945,184
Restricted stock units subject to future vesting	219,609	434,790	—
Total	13,330,326	10,119,600	6,945,184

16. Related Party Transactions

In connection with the resignation of John Fowler from his role as Chief Executive Officer, the Company and Mr. Fowler entered into a Separation and Consulting Agreement, effective as of November 7, 2023 (the "Fowler Agreement"), pursuant to which Mr. Fowler provides consulting services to the Company at a rate of $5,000 per month for one year ending November 7, 2024. Pursuant to the Fowler Agreement, the Company recognized approximately $9,000 of compensation expense within general and administrative expenses in the Consolidated Statement of Operations during the three months ended December 31, 2023.

In connection with the resignation of Christopher Kirk, Ph.D. from his role as President and Chief Scientific Officer of the Company, the Company and Dr. Kirk entered into an Advisor Agreement, effective as of April 22, 2023 (the "Kirk Agreement"), pursuant to which Dr. Kirk provided scientific and strategic advisory services as a consultant to the Company (the "Services"). The Services were provided at a rate of $41,050 per month, and the Company reimbursed Dr. Kirk for the cost of premiums for continued COBRA coverage through the termination date of the

Advisor Agreement. The Kirk Agreement was terminated on November 7, 2023 in connection with Dr. Kirk's appointment as the Company's Chief Executive Officer. Pursuant to the Kirk Agreement, the Company recognized and paid approximately $267,000 of compensation expense within research and development expenses in the Consolidated Statement of Operations in 2023.

17. Restructuring and Impairment Charges

In October 2023, the Company announced a strategic restructuring and workforce reduction (the "Workforce Reduction") to prioritize its clinical-stage assets, extend the cash runway and reduce the total workforce. All employees affected by the Workforce Reduction separated from the Company by December 31, 2023. In connection with the Workforce Reduction, the Company committed to a plan to sublease Suite 400 of its corporate headquarters which resulted in an impairment to the right-of use asset and certain property and equipment no longer utilized under current or expected future operations.

The Company recognized cumulative restructuring charges of $6.2 million, comprised primarily of one-time employee termination benefits and long-lived assets impairment costs during the year ended December 31, 2023. Restructuring and impairment charges, recorded in the Consolidated Statement of Operations are presented in the table below (in thousands):

	Year ended December 31, 2023
Severance and related benefit costs	$ 3,279
Asset impairments	2,908
Total	$ 6,187

The following table illustrates the accrual activity and payments relating to restructuring and impairment charges (in thousands):

	Severance and related benefit costs	Asset impairments	Total
Balance as of January 1, 2023	$ —	$ —	$ —
Restructuring charges	3,279	2,908	6,187
Cash payments made	(1,858)	—	(1,858)
Non-cash charges	—	(2,908)	(2,908)
Balance as of December 31, 2023	$ 1,421	$ —	$ 1,421

As of December 31, 2023, $1.4 million of severance and related benefit costs are included in accrued liabilities in the Consolidated Balance Sheet. We expect that substantially all of the remaining accrued restructuring liabilities will be paid in cash over next nine months.

Stockholder Information

BOARD OF DIRECTORS

Graham Cooper
Chairman
Formerly of
Assembly Biosciences

Franklin Berger
FMB Research

John Fowler
Formerly of
Kezar Life Sciences

Elizabeth Garner, M.D.
Ferring Pharmaceuticals

Michael Kauffman, M.D., Ph.D.
Nereid Therapeutics Inc.

Christopher Kirk, Ph.D.
Kezar Life Sciences

Micki Klearman, M.D.
Formerly of
Genentech

Courtney Wallace
Third Rock Ventures

EXECUTIVE OFFICERS

Christopher Kirk, Ph.D.
Chief Executive Officer

Marc Belsky
Chief Financial Officer

Nick Mordwinkin, Ph.D.
Chief Business Officer

Mark Schiller
Chief Legal Officer

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INVESTOR RELATIONS

A copy of our 2023 Annual Report on Form 10-K filed with the Securities and Exchange Commission (which accompanies and forms part of this 2023 Annual Report to Stockholders) is available without charge to any stockholder upon written request.

For investor relations inquiries, or to request a copy of our 2023 Annual Report, contact: ir@kezarbio.com

STOCK EXCHANGE

Our common stock is listed on The Nasdaq Stock Market under the symbol “KZR.”