

Risk Factors Comparison 2025-03-25 to 2024-03-14 Form: 10-K

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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 our collaboration with 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 Since inception in February 2015, we have incurred significant operating losses. Our net loss was \$ 83.7 million, \$ 101.9 million, and \$ 68.2 million and \$ 54.6 million for the years ended December 31, 2024, 2023, and 2022 and 2021, respectively. As of December 31, 2023-2024, we had an accumulated deficit of \$ 350.434.85 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 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. 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~~ **2024**, we had cash, cash equivalents and marketable securities of \$ ~~201.132~~ **4.2** million. We believe that our ~~existing~~ cash, cash equivalents and marketable securities as of December 31, ~~2023~~ **2024** 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. 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 ~~a Sales sales Agreement 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~~ **2024**, approximately \$ 68. 3 million remains available under the at- the- market **offering** 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 **our product candidates 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 **our former product candidates such as** 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 or any future product candidates** in a timely manner. **Our** **For example, in October 2024, we terminated our PALIZADE Phase 2b clinical trial evaluating zetomipzomib in patients with LN to focus our clinical development efforts of zetomipzomib in AIH. This and other** 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. 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. **Delays in or failure to complete any preclinical studies or clinical trials of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. For example, in October 2024, we terminated our global PALIZADE Phase 2b clinical trial evaluating zetomipzomib in patients with LN after the trial was placed on clinical hold by the FDA. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.** Failure can occur at any stage, and we could encounter problems that cause us to suspend, abandon or repeat clinical trials. **Any delays to our PALIZADE** is a global, placebo-controlled, double-blind Phase 2b clinical **preclinical studies** 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 **or performed clinical trials, that occur as a result could shorten any period during which we**. The process and timelines required to obtain approval from foreign regulatory authorities is unpredictable and may **have depend upon numerous factors and their** **the substantial discretion. The exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial inability** **viability to obtain and maintain regulatory approval for** **of our product candidates could be significantly reduced. Any of the these occurrences** **conduct of the PALIZADE trial outside the United States may impact the timelines** **harm our business, financial condition and prospects significantly** **completion of the PALIZADE trial**. If the market opportunities for zetomipzomib and **KZR-261** or any future product candidates 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 **AIH** **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 **a product candidate like 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. **For example, in October 2024, we terminated our global PALIZADE Phase 2b trial evaluating zetomipzomib in patients with LN after the trial was placed on clinical hold by the FDA and focused our clinical development efforts of zetomipzomib in AIH.** 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. 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~~ **any other** strategic ~~collaboration~~ **collaborations** 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 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, **although results in May 2022, we reported topline data from our PRESIDIO the MISSION Phase 2 clinical trial of evaluating zetomipzomib demonstrated positive complete results, in October 2024, we terminated our global PALIZADE Phase 2b clinical trial evaluating zetomipzomib in patients with LN after the trial was dermatomyositis and polymyositis, in which zetomipzomib did not demonstrate significant differentiation from placebo placed on clinical hold by the FDA.** 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. 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~~ **October 2022-2024**, we ~~terminated~~ **reported topline data from** our **PRESIDIO global PALIZADE Phase 2-2b clinical trial of evaluating** zetomipzomib in patients with **LN after the trial was** ~~dermatomyositis and polymyositis, in which zetomipzomib did not demonstrate significant differentiation from placebo~~ **placed on clinical hold by the FDA**. 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, **such as the clinical hold imposed by the FDA on our PALIZADE Phase 2b clinical trial of zetomipzomib in patients with LN following four patient deaths in the Philippines and Argentina**, 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. **For example, in October 2024, we terminated our PALIZADE Phase 2b clinical trial evaluating zetomipzomib in patients with LN. This decision was made after the trial was placed on clinical hold by the FDA following four patient deaths in the Philippines and Argentina.** 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 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, **allowing 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. 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. **For example, in October 2024, we terminated our PALIZADE Phase 2b clinical trial evaluating zetomipzomib in patients with LN. This decision was made after the trial was placed on clinical hold by the FDA following four deaths in patients enrolled in the trial in the Philippines and Argentina.** 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. 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 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~~ **territory** during the term of the Everest License Agreement ranging from the single digit to the low- teens, subject to certain reductions. Everest ~~is~~ **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 agreed to~~ collaborate with Everest on the PALIZADE trial, where Everest ~~will would~~ have primary responsibility for clinical development and regulatory activities in the licensed territory and ~~will would~~ 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 **at any time** following **the October 2024** ~~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 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. 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 zetemipzomib or ~~KZR-261~~ **any future product candidates**, which could make it difficult for us to sell profitably, if approved. Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which coverage and reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One third-party payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. **Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.** 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 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 ~~for~~ 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 and amendments 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 second Trump 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 was signed into law, which eliminates eliminated the statutory Medicaid drug rebate cap, currently previously 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 the IRA was signed the Inflation Reduction Act of 2022, or the IRA, into law, which included a number of significant drug pricing reforms, including (i) 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 high-expenditure, single-source drugs that have been on the market for at least seven years or pay an excise tax for noncompliance, (ii) the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation, and (iii) 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 Drug price Price negotiation Negotiation program Program is currently subject to legal challenges. HHS 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 agreed-upon price of the first ten drugs that were will be subject to price negotiations and on January 17, although they may be the Medicare drug 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 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 2025 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. **The Under the Quality Payment Program consists of two payment tracks that eligible clinicians can participate in: Advanced Alternative Payment Models and the Merit-Based Incentive Payment System. Under both the Advanced Alternative Payment Models and the Merit-Based Incentive Payment System**, 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. **The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create** Additionally-- **additional uncertainty for our business. These actions may**, based on for example, **include directives to reduce agency workforce, rescinding a recent prior administration executive order --tasking the CMMI to consider new payment and healthcare models to limit drug spending and eliminating** the Biden administration's executive order that expressed its intent to pursue certain policy initiatives to reduce drug prices and directed HHS to **establishing an AI task** submit a report on how the Center for **force and developing a strategic plan. Additionally, in its June 2024 Loper Bright decision, the U. S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass healthcare-related legislation that could impact the drug approval process and make changes to the** Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug **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 **Price Negotiation Program created under** 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-- **the IRA 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. **The FDA's ability to review and approve new products may be hindered by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, statutory, regulatory and policy changes and global health concerns. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions and could greatly impact healthcare and the pharmaceutical industry**. 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. **For any activities conducted in China, we are exposed to the increased possibility of supply disruptions and higher costs in the event of changes in the policies of the U. S. or Chinese governments, political unrest or unstable economic conditions including sanctions on China or any of our China- based suppliers. Our manufacturing costs could also increase as a result of future appreciation of the local currency in China or increased labor costs if the demand for skilled laborers increases and / or the availability of skilled labor declines in China. In addition, certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U. S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, the recently proposed BIOSECURE Act introduced in the U. S. House of Representatives, and a substantially similar bill in the U. S. Senate, target U. S. government contracts, grants, and loans for entities that use equipment and services from certain named Chinese biotechnology companies and authorizes the U. S. government to include additional Chinese biotechnology companies of concern. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability of companies to work with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U. S. government. Such disruption could have adverse effects on the development of our product candidates and our business operations.** 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 ~~oversaw will oversee~~ their performance and ~~maintain maintained~~ certain regulatory responsibilities, ~~we were the ultimate~~ success of initiating, enrolling and completing this trial, and ensuring regulatory and quality compliance across several countries, will depend **dependent significantly in large part** 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. 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~~ **any future product candidates** 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 **our product candidates** 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 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 **and the third parties with whom we work** are subject to stringent and changing U. S. and foreign laws, regulations, **, rules, and contractual** and other obligations related to data privacy and security. Our actual or perceived failure, **or that of the third parties with whom we work,** 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 **and may become subject to additional such obligations in the future.** 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, and other similar** 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. **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 and increase compliance costs.** If we become subject to new data privacy **or security** 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 with** whom we **rely work**. 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,~~ **Under the EU and 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. **Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. For example, regulators in the United States including the Department of Justice are increasingly scrutinizing certain personal data transfers and taking steps to enact certain data localization requirements, such as the Department of Justice's recently finalized rule implementing the Biden Administration's executive order "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern."** 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 **statements about** compliance with certain certifications or self-regulatory principles, **regarding concerning** data privacy and security. **If Regulators in the United States are increasingly scrutinizing these statements, and if** these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, **misleading** or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. **Our employees and personnel may use generative artificial intelligence, or AI, technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. The use of this technology by our employees or personnel could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If our employees and personnel are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. 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 with whom we rely work** 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. **If Significant disruptions of our, or our our contractors' or vendors', information technology systems, or those third parties with whom we work, or or our data security incidents are or were compromised, we could experience adverse consequences result resulting in significant financial from such compromise. legal, including but not limited to** regulatory **investigations or actions; litigation; fines and penalties; disruptions of our business and operations; reputational harm to us; loss of revenue or profits; and other adverse consequences.** In the ordinary course of our business, we and the third parties **upon which with whom we rely work** 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 with whom we rely work**. 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 cyber-attacks**, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties **upon which with whom we rely work** may be vulnerable to a heightened risk of these attacks, including **cyberattacks cyber-attacks** that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. 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. **It may be difficult and / or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.** 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 work~~). **We have not in the past detected and remediated all such vulnerabilities, including on a timely basis, and may not do so in the future.** Further, we ~~have experienced, and may in the future 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~~ **Certain** of the previously identified or similar threats ~~could have in the past and may in the future~~ 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 which we rely work~~ . **For example, we have been the target of unsuccessful phishing attempts in the past and expect such attempts will continue in the future.** A security incident could disrupt our ability (and that of third parties ~~upon which we rely work~~) 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 have~~ **require required** 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 **also** 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 which we rely work~~) 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 **2023-2024**, the closing price of our common stock on The Nasdaq Global Select Market ranged from **\$ 7-10.31-50** per share to **\$ 0-5.72-30** per share, **as adjusted for our October 2024 one-for-ten reverse stock split, or Reverse Stock Split**. 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 zetemipzomib, ~~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, **such as the termination of our PALIZADE Phase 2b clinical trial of zetemipzomib in patients with LN**;
- 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. 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. 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, due to reasons including, among other things, political changes and trends such as protectionism, economic nationalism resulting in government actions impacting international trade agreements or imposing trade restrictions such as tariffs and retaliatory counter measures. 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. **We cannot predict the ultimate effect on our common stock share price of the Reverse Stock Split. The Reverse Stock Split may decrease the liquidity of our common stock and magnify any decrease in our overall market capitalization. The ultimate effect of the Reverse Stock Split on the market price of our common stock cannot be predicted with any certainty, and we cannot assure you that the Reverse Stock Split will result in any or all of the benefits we expect, including enabling the Company to regain compliance with the Nasdaq listing standards, for any meaningful period of time. While we expect that the reduction in the number of outstanding shares of common stock will proportionally increase the market price of our common stock, we cannot assure you that the Reverse Stock Split will increase the market price of our common stock by a multiple of the Reverse Stock Split ratio or result in any permanent or sustained increase in the market price of our common stock. The market price of our common stock depends on multiple factors, many of which are unrelated to the number of shares outstanding, including our business and financial performance, general market conditions and prospects for future success, any of which could have a counteracting effect to the Reverse Stock Split on the per share price. In addition, the Reverse Stock Split also reduced the total number of outstanding shares of common stock, which may lead to reduced trading for our common stock, which is already generally thinly traded. As a result of a lower number of shares outstanding, the market for our common stock may also become more volatile. The Reverse Stock Split also increased the number of stockholders who own " odd lots " of less than 100 shares of common stock. A purchase or sale of less than 100 shares of common stock (an " odd lot " transaction) may result in incrementally higher trading costs through certain brokers, particularly " full service " brokers. Therefore, those stockholders who own fewer than 100 shares of common stock following the Reverse Stock Split may be required to pay higher transaction costs if they sell their common stock.** 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, 2023-2024, 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 40.38 % 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 2/3 % of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws. Moreover, **In addition, our charter contains a provision that authorizes our board of directors to issue preferred stock without stockholder approval, which has been and could in the future 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. In October 2024, our board of directors implemented a limited duration stockholder rights plan and declared a dividend of one preferred share purchase right, or a Right, for each outstanding share of the Company’ s common stock as of the close of business on October 28, 2024, or the Rights Plan. The Rights Plan was adopted in response to (i) the unsolicited, non- binding proposal from Concentra Biosciences, LLC, or Concentra, to acquire all of the outstanding shares of Company’ s common stock for cash consideration of \$ 1. 10 per share, plus a contingent value right that represents the**

right to receive 80 % of the net proceeds from any out-license or disposition of the Company's development programs or intellectual property, and (ii) Concentra and its affiliates' rapid accumulation of 9.9 % of the outstanding Company's common stock. The Rights Plan may have the effect of discouraging or preventing a change of control by, among other things, making it uneconomical for a third party to acquire us without the consent of our board of directors, although there can be no guarantee that the Rights Plan will fulfill its intended purpose. The Rights will expire on October 17, 2025, unless the Rights are earlier redeemed or exchanged by us. Furthermore, 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.