

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

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Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading “ Risk Factors ” and should be carefully considered, together with other information in this Annual Report on Form 10- K and our other filings with the SEC before making an investment decision regarding our common stock. • We have incurred significant operating losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability. • We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts. • Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. • Our limited operating history may make it difficult for ~~you~~ investors to evaluate the success of our business to date and to assess our future viability. • Our future success depends on our ability to retain key executives and to attract, retain, and motivate qualified personnel. • We depend heavily on the future success of KIO- 104 and KIO- 301. If we are unable to successfully obtain marketing approval for KIO- 104, or KIO- 301, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize KIO- 104 or KIO- 301, our business will be materially harmed. • If clinical trials of KIO- 104, KIO- 301, or any other product candidate that we may develop fail to demonstrate safety and efficacy to the satisfaction of the FDA or foreign regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of KIO- 104, KIO- 301, or any other product candidate. • Even if KIO- 104, KIO- 301, or any other product candidate that we may develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success and the market opportunity for our product candidates may be smaller than we estimate. • If we are unable to establish sales, marketing, and distribution capabilities, we may not be successful in KIO- 104, KIO- 301, or any other product candidates that we may develop if and when they are approved. • We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do. • Even if we are able to commercialize KIO- 104, KIO- 301, or any other product candidate that we may develop, the products may become subject to unfavorable pricing regulations, third- party coverage or reimbursement practices, or healthcare reform initiatives which could harm our business. • We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials. • If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired. • We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming, and unsuccessful. • 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 material adverse effect on the success of our business. • If we are not able to obtain required regulatory approvals, we will not be able to commercialize KIO- 104, KIO- 301, or any other product candidate that we may develop; and our ability to generate revenue will be materially impaired. • We incur increasing costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices. • 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. • If we identify a material weakness in our internal control over financial reporting in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely meet requirements applicable to public companies, which may adversely affect investor confidence in us, and, as a result, the market price of our common stock. The following factors should be reviewed carefully, in conjunction with the other information contained in this Annual Report on Form 10- K. As previously discussed, our actual results could differ materially from our forward- looking statements. Our business faces a variety of risks. These risks include those described below and may include additional risks and uncertainties not presently known to us or that we currently deem immaterial. If any of the events or circumstances described in the following risk factors occur, our business operations, performance, and financial condition could be adversely affected and the trading price of our common stock could decline. Risks Related to Our Financial Position and Need for Additional Capital Since inception, we have incurred significant operating losses. Our net ~~loss~~ income was approximately \$ ~~12.3~~ 5.6 million for the year ended December 31, ~~2023~~ 2024 ~~-,~~ Our net loss was \$ ~~13.12~~ 6.5 million for the year ended December 31, ~~2022~~ 2023 and \$ ~~147.143~~ 0.4 million from the period of inception (December 28, 2004) through December 31, ~~2023~~ 2024. To date, we have financed our operations primarily through private placements and public offerings of our securities, and payments from our license agreements. We have devoted substantially all of our financial resources and efforts to research and development, including ~~pre-clinical~~ preclinical studies and, beginning in 2008, clinical trials. We are still in the development stage of our product candidates , and we have not completed development of any drugs. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will continue to be significant with the clinical trials for the ongoing development of our KIO- 104 and KIO- 301 products. Our expenses will also increase if and as we: • seek marketing approval for KIO- 104 and KIO- 301, whether alone or

in collaboration with third parties; • continue the research and development of KIO- 104 , ~~and~~ KIO- 301 , ~~and any of our other product candidates~~; • seek to develop additional product candidates; • in- license or acquire the rights to other products, product candidates, or technologies; • seek marketing approvals for any product candidates that successfully complete clinical trials; • establish sales, marketing, and distribution capabilities and scale up and validate external manufacturing capabilities to commercialize any products for which we may obtain marketing approval; • maintain, expand and protect our intellectual property portfolio; • hire additional clinical, quality control, scientific and management personnel; • expand our operational, financial and management systems, and personnel, including personnel to support our clinical development, manufacturing, and planned future commercialization efforts and our operations as a public company; and • increase our insurance coverage as we expand our clinical trials and commence commercialization of KIO- 104 and KIO- 301 . Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase if: • we are required by the FDA or foreign equivalents to perform studies or clinical trials in addition to those currently expected , and • there are any delays in ~~patient~~ enrollment of patients in or in completing our ~~the~~ clinical trials or the development of KIO- 104 , KIO- 301 , or any other product candidates that we may develop. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and commercialize KIO- 104 , KIO- 301 , or other product candidates that we may develop, which may never occur. This will require us to be successful in a range of challenging activities, including: • establishing collaboration, distribution, or other marketing arrangements with third parties to commercialize KIO- 104 and KIO- 301 in markets outside the U. S. ; • achieving an adequate level of market acceptance of our product candidates; • protecting our rights to our intellectual property portfolio related to our product candidates; and • ensuring the manufacture of commercial quantities of KIO- 104 and KIO- 301 . 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 depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings, or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. We expect to devote substantial financial resources to our ongoing and planned activities, particularly continuing the clinical development of our KIO- 104 and KIO- 301 ~~products~~ **product candidates** . In the future, we expect to raise additional financial resources for the continued clinical development of KIO- 104 , KIO- 301 , and other product candidates we may develop. In addition, if we obtain regulatory approval for any of our product candidates, we would need to devote substantial financial resources to commercialization efforts, including product manufacturing, marketing, sales, and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce, or eliminate our research and development programs or any future commercialization efforts. Our future capital requirements will depend on many factors, including: • the progress, costs, and outcome of our clinical trials for our product candidates and of any clinical activities required for regulatory review of our product candidates outside of the U. S. ; • the costs and timing of process development and manufacturing scale up and validation activities associated with our product candidates; • the costs, timing, and outcome of regulatory review of our product candidates in the U. S. , and in other jurisdictions; • the costs and timing of commercialization activities for our product candidates if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution, and outsourced manufacturing capabilities; • subject to receipt of marketing approval, the amount of revenue received from commercial sales of our product candidates; • our ability to establish collaborations on favorable terms, if at all, particularly manufacturing, marketing, and distribution arrangements for our product candidates; • the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property- related claims; and • the extent to which we in- license or acquire rights to other products, product candidates, or technologies for the treatment of ophthalmic diseases. As of December 31, ~~2023~~ **2024** , we had cash and cash equivalents of \$ ~~3~~ **2.5** million. ~~Subsequent to year- end, in January 2024, we entered into a strategic development and commercialization agreement with TOI receiving an upfront payment of \$ 16 million. Additionally, in January 2024, we completed a private placement transaction raising net proceeds of approximately \$ 13.8 million and short- term investments of \$ 23.0 million for a total of \$ 26.8 million .~~ With the current cash ~~and short- term investments~~ on hand, we believe we will have sufficient cash to fund planned operations into ~~2026~~ **2027** , however, the acceleration or reduction of cash outflows by management can significantly impact the timing needed for raising additional capital to complete development of our products. To continue development, we will need to raise additional capital through debt and / or equity financing or access additional funding through U. S. or foreign grants. Although we completed our initial public offering and subsequent public offerings, registered direct offerings and private placements, additional capital may not be available on terms favorable to us, if at all. Accordingly, no assurances can be given that management will be successful in these endeavors. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should we be unable to continue as a going concern. Identifying potential product candidates and conducting ~~pre- clinical~~ **preclinical** testing and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. Our commercial revenues, if any, will be derived from sales of KIO- 104 , KIO- 301 , or any other ~~products~~ **product candidates** that we successfully develop, none of which we expect to be commercially available for several years, if at all. In addition, if approved, any product candidate that we develop or any product that we in- license may not achieve commercial success. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even

if we believe we have sufficient funds for our current or future operating plans. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third- party funding, collaborations, strategic alliances, licensing arrangements, and marketing and distribution arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we cannot raise funds on acceptable terms, we may not be able to grow our business or respond to competitive pressures. If we raise additional funds through government **grants** or other third- party funding, collaborations, strategic alliances, licensing arrangements, or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts, or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves. We are a clinical- stage company with a limited operating history. Our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies, and conducting clinical trials of KIO- 104 and KIO- 301. We have not yet demonstrated our ability to successfully complete development of a product candidate, obtain marketing approvals, manufacture at commercial scale, or arrange for a third party to do so on our behalf, or conduct sales, marketing, and distribution activities necessary for successful product commercialization. In addition, as a pre- revenue business, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter- to- quarter and year- to- year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. **Taxing authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability. We are organized in the United States, and have wholly- owned subsidiaries in United States, Austria and Australia. If we succeed in growing our business, we may conduct increased operations through subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that such arrangements be priced the same as those between unrelated companies dealing at arm’ s length and that appropriate documentation is maintained to support the value of such arrangements. Our transfer pricing policies were formulated with the assistance of third- party experts; however, tax authorities in any country may disagree with our transfer pricing policies and procedures and we are subject to more tax audits as a result of having subsidiaries in foreign countries. If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm’ s length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties it would increase our tax liability, which could adversely affect our financial condition, results of operations and cash flows.** Foreign currency exchange rate fluctuations may have a negative impact on our financial results. We are subject to the risks of fluctuating foreign currency exchange rates, which could have an adverse effect on the costs and expenses of our foreign subsidiaries. As a result, currency fluctuations among the U. S. dollar, euro, Australian dollar, and the other currencies in which we do business have caused and will continue to cause foreign currency translation and transaction gains and losses. We have not used forward exchange contracts to hedge our foreign currency exposures. In the future, we may undertake to manage foreign currency risk through hedging methods, including foreign currency contracts. We recognize foreign currency gains or losses arising from our operations in the period incurred. We cannot guarantee that we will be successful in managing foreign currency risk or in predicting the effects of exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposure, and the potential volatility of currency exchange rates. We cannot predict with any certainty changes in foreign currency exchange rates or the degree to which we can address these risks. Risks Related to the Discovery and Development of Our Product Candidates We depend heavily on the success of KIO- 104 and KIO- 301. If we are unable to successfully obtain marketing approval for KIO- 104 and KIO- 301, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize KIO- 104 and KIO- 301, our business will be materially harmed. We have invested a significant portion of our efforts and financial resources in the development of KIO- ~~104~~ **104** and KIO- ~~201-301~~ **301**, and we expect to invest a significant portion of our efforts and financial resources in the development of KIO- 104 and KIO- 301 in the future. There remains a significant risk that we ~~will~~ **may** fail to successfully develop either product candidate. We cannot accurately predict when or if KIO- 104 or KIO- 301 will prove effective or safe in humans or whether it will receive marketing approval. Our ability to generate product revenues, which may never occur, will depend heavily on ~~our~~ **obtaining marketing approval to for and commercializing commercialize** KIO- 104 and KIO- 301. The success of KIO- 104 and KIO- 301 will depend on several factors, including the following: • obtaining favorable results from clinical trials; • applying for and receiving marketing approvals from applicable regulatory authorities for KIO- 104 and KIO- 301; • making arrangements with third- party manufacturers for commercial quantities of KIO- 104 and KIO- 301 and receiving

regulatory approval of our manufacturing processes and our third- party manufacturers' facilities from applicable regulatory authorities; • establishing sales, marketing, and distribution capabilities and launching commercial sales of KIO- 104 and KIO- 301, if and when approved, whether alone or in collaboration with others; • acceptance of KIO- 104 and KIO- 301, if and when approved, by patients, the medical community, and third- party payors; • effectively competing with other therapies, including the existing standard- of- care; • maintaining a continued acceptable safety profile of KIO- 104 and KIO- 301 following approval; • obtaining and maintaining coverage and adequate reimbursement from third- party payors; • obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and • protecting our rights in our intellectual property portfolio related to KIO- 104 and KIO- 301. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize KIO- 104 and KIO- 301, which would materially harm our business. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete ~~pre-clinical~~ **preclinical** development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, ~~pre-clinical~~ **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. If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize KIO- 104, KIO- 301, or any other product candidates that we may develop, including: • clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; • the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate; • any third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites; • we may decide, or regulators or institutional review boards may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; • the cost of clinical trials of our product candidates may be greater than we anticipate; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and • our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, or institutional review boards to suspend or terminate the trials. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not favorable or are only modestly favorable or if there are safety concerns, we may: • be delayed in obtaining marketing approval for our product candidates; • not obtain marketing approval 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 subject to additional post- marketing testing requirements; or • have the product removed from the market after obtaining marketing approval. Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant ~~pre-clinical~~ **preclinical** or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates. If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. We may not be able to initiate or continue clinical trials for KIO- 104 and KIO- 301, or our other product candidates that we may develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U. S. In addition, some of our competitors may have ongoing clinical trials for product candidates that treat the same indications as KIO- 104 and KIO- 301, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether, and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. If serious adverse or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of such product candidates. If KIO- 104, KIO- 301, or any of our other product candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects, or other characteristics are less prevalent, less severe, or more acceptable from a risk- benefit perspective. Many compounds that initially showed promise in clinical or early- stage testing for treating ophthalmic disease have later been found to cause side effects that prevented further development of the compound. We may expend our limited resources to pursue a particular product candidate or indication and

fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. To the extent our contemplated trials are unsuccessful, we may not be able to raise additional funds for subsequent trials or pursuing other indications. Risks Related to the Commercialization of Our Product Candidates Even if KIO- 104, KIO- 301, or any other product candidate that we **may** develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors, and others in the medical community necessary for commercial success and the market opportunity for our product candidates may be smaller than we estimate. If KIO- 104, KIO- 301, or any other product candidate that we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors, and others in the medical community. Our assessment of the potential market opportunity for KIO- 104 and KIO- 301 is based on industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties. Industry publications and third- party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. If the actual market for KIO- 104 and KIO- 301 is smaller than we expect, our product revenue may be limited, and it may be more difficult for us to achieve or maintain profitability. If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in KIO- 104, KIO- 301, or any other product candidates that we may develop if and when they are approved. We do not have a sales or marketing infrastructure. To achieve commercial success for any product for which we have obtained marketing approval and have not licensed the commercialization rights, we will need to establish sales, marketing, and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties. In the future, we plan to build sales and marketing infrastructure to market or co- promote KIO- 104, KIO- 301, and possibly other product candidates that we **may** develop, if and when they are approved. There are risks involved with establishing our own sales, marketing, and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of KIO- 104, KIO- 301, or any other product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize product candidates on our own include: • our inability to recruit, train, and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our products; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. We expect to enter into arrangements with third parties to perform consulting, sales, marketing, and distribution services in markets outside the U. S. We may also enter into arrangements with third parties to perform these services in the U. S. if we do not establish our own sales, marketing, and distribution capabilities in the U. S., or if we determine that such third- party arrangements are otherwise beneficial. Our product revenues and our profitability, if any, under any such third- party sales, marketing, or distribution arrangements are likely to be lower than if we were to market, sell, and distribute our product candidates. In addition, we may not be successful in entering into arrangements with third parties to sell, market, and distribute our product candidates, or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales, marketing, and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing KIO- 101, KIO- 104, KIO- ~~201~~, KIO- 301, or any other product candidates that we may develop. The development and commercialization of new drug products is highly competitive. We face competition with respect to KIO- 104, KIO- 301, and our other current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. 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. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than our product candidates. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third- party payors, particularly Medicare, seeking to encourage the use of generic products. Generic products are currently being used for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If KIO- 104, KIO- 301, or any other product candidate that we may develop achieves marketing

approval, we expect that it will be priced at a premium over competitive products. Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, ~~pre-clinical~~ **preclinical** testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. 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 other 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 and management personnel, establishing clinical trial sites, and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Even if we are able to commercialize KIO- 104, KIO- 301, or any other product candidate that we may develop, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices, or healthcare reform initiatives, which could harm our business. Our ability to commercialize KIO- 104, KIO- 301, or any other product candidates that we may develop successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, managed care plans, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for our product candidates and, even if they are available, the level of reimbursement may not be satisfactory. Inadequate reimbursement may adversely affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the U. S. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U. S. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop would compromise our ability to generate revenues and become profitable. The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sales price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. There can be no assurance that our product candidates or any products that we may in-license, if they are approved for sale in the U. S. or in other countries, will be considered medically reasonable and necessary for a specific indication, that they will be considered cost-effective by third-party payors, that coverage and an adequate level of reimbursement will be available, or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably. Our strategy of obtaining rights to product candidates and approved products through in-licenses and acquisitions may not be successful. We may expand our product pipeline through opportunistically in-licensing or acquiring the rights to other products, product candidates, or technologies. The future growth of our business may depend in part on our ability to in-license or acquire the rights to approved products, additional product candidates, or technologies. However, we may be unable to in-license or acquire the rights to any such products, product candidates, or technologies from third parties. The in-licensing and acquisition of pharmaceutical products is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire products, product candidates, or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash 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 in-license or acquire the rights to the relevant product, product candidate, or technology on terms that would allow us to make an appropriate return on our investment. Furthermore, we may

be unable to identify suitable products, product candidates, or technologies within our area of focus. If we are unable to successfully obtain rights to suitable products, product candidates or technologies, our ability to pursue this element of our strategy could be impaired. Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we develop. We face an inherent risk of product liability exposure related to the use of the product candidates that we develop in human clinical trials and will face an even greater risk if we commercially sell any products that we develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates or products that we develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • significant costs to defend the related litigation; • substantial monetary awards to trial participants or patients; • loss of revenue; • reduced time and attention of our management to pursue our business strategy; and • the inability to commercialize any products that we develop. While we obtain insurance for each clinical trial we perform, we may not be adequately insured to cover all liabilities that we may incur. We will need to increase our insurance coverage as we expand our clinical trials. We will need to further increase our insurance coverage if we commence commercialization of any product candidate that receives marketing approval. 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 Our Dependence on Third Parties We may enter into collaborations with other third parties for the development or commercialization of our product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates. We expect to utilize a variety of types of collaboration, distribution, and other marketing arrangements with third parties to commercialize KIO- 104 and KIO- 301 in markets outside the U. S. We also may enter into arrangements with third parties to perform these services in the U. S. if we do not establish our own sales, marketing, and distribution capabilities in the U. S., or if we determine that such third- party arrangements are otherwise beneficial. On January 25, 2024, we entered into an agreement with TOI relating to KIO- 301, which grants TOI global rights (except for certain countries in Asia) to co- develop and co- commercialize KIO- 301 in ophthalmology. We also may seek third- party collaborators for development and commercialization of other product candidates. Our likely collaborators for any sales, marketing, distribution, development, licensing, or broader collaboration arrangements include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If we do not receive the funding we expect under any future collaboration agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval, and commercialization described in this Annual Report on Form 10- K also apply to the activities of our collaborators. Additionally, subject to its contractual obligations to us, if a collaborator of ours were to be involved in a business combination, it might de- emphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be harmed.

We are dependent on TOI for the successful co- development and commercialization of KIO- 301. If TOI does not devote sufficient resources to the co- development and commercialization of KIO- 301, are unsuccessful in their efforts, or chooses to terminate their agreement with us, the potential revenue may not materialize. In January 2024, we entered into a strategic co- development and commercialization agreement with TOI. Under the agreement, we granted TOI exclusive worldwide co- development and commercialization rights, excluding certain countries in Asia, to KIO- 301 for the treatment of degenerative retinal diseases. In exchange, we received an upfront payment of \$ 16 million, and will be eligible to receive up to \$ 285 million upon achievement of pre- specified clinical development, regulatory and commercial milestones, tiered royalties of up to low 20 % on net sales; and reimbursement of certain KIO- 301 research and development expenses. Under the agreement, TOI is solely and exclusively responsible for all costs and activities related to Phase III clinical trials for KIO- 301. TOI may determine, however, that it is commercially reasonable to de- prioritize or discontinue the development of the KIO- 301. These decisions may occur for many reasons, including internal business reasons, results from clinical trials or because of unfavorable regulatory feedback. Further, on review of the safety and efficacy data, the FDA may impose requirements on the programs that render them commercially nonviable. In addition, under the agreement, TOI has certain decision- making rights in determining the development and commercialization plans and activities for the programs. We may disagree with TOI about the development strategy they employ, but we will have limited rights to impose our development strategy on TOI. Similarly, TOI may decide to seek marketing approval for, and limit commercialization of KIO- 301 to narrower indications than we would pursue. More broadly, if TOI elects to discontinue the development of KIO- 301, we may be unable to advance the product candidate ourselves.

If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the U. S., the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a

challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform. We have relied on third parties, such as contract research organizations (CROs) to conduct our completed trials of our product candidates, and do not plan to independently conduct clinical trials of our product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our clinical trials. These agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that would delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. We contract with third parties for the manufacture of KIO- 104 and KIO- 301 for clinical trials and expect to continue to do so in connection with the commercialization of KIO- 104, KIO- 301, and for clinical trials and commercialization of any other product candidates that we may develop. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of KIO- 104, KIO- 301, or any other of our product candidates. We rely, and expect to continue to rely, on third parties to manufacture clinical and commercial supplies of KIO- 104 and KIO- 301, ~~pre-clinical~~ **preclinical** and clinical supplies of our other product candidates that we may develop, and commercial supplies of products if and when any of our product candidates receive marketing approval. Our current and anticipated future dependence upon others for the manufacture of KIO- 104, KIO- 301, and any other product candidate or product that we develop, may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. In addition, any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We currently rely exclusively on third-party manufacturers to assemble and prepare KIO- 104 and KIO- 301 on a purchase order basis. We do not currently have any contractual commitments for commercial supply of bulk drug substance for KIO- 104, KIO- 301, or fill-finish services. We also do not currently have arrangements in place for redundant supply or a second source for bulk drug substance for KIO- 104 and KIO- 301, or for fill-finish services. The prices at which we are able to obtain supplies of KIO- 104, KIO- 301, and fill-finish services may vary substantially over time and adversely affect our financial results. If our third-party manufacturers for KIO- 104 or KIO- 301 fail to fulfill our purchase orders or should become unavailable to us for any reason, we believe that there are a limited number of potential replacement manufacturers, and we likely would incur added costs and delays in identifying or qualifying such replacements. We could also incur additional costs and delays in identifying or qualifying a replacement manufacturer for fill-finish services if our existing third-party manufacturer should become unavailable for any reason. We may be unable to establish any agreements with such replacement manufacturers or to do so on acceptable terms. Even if we could transfer manufacturing to a different third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA approval before using or selling any products manufactured at that facility. In connection with our application for a license to market KIO- 104, KIO- 301, or other product candidates in the U. S., we may be required to conduct a comparability study if the product we intend to market is supplied by a manufacturer different from the one who supplied the product evaluated in our clinical studies. Delays in designing and completing this study to the satisfaction of the FDA could delay or preclude our development and commercialization plans and thereby limit our revenues and growth. Reliance on third-party manufacturers entails additional risks, including: • KIO- 104, KIO- 301, and any other product candidates that we may develop may compete with other product candidates and products for access to a limited number of suitable manufacturing facilities that operate under current good manufacturing practices or CGMP regulations; • reliance on the third party for regulatory

compliance and quality assurance; • the possible breach of the manufacturing agreement by the third party; • the possible misappropriation of our proprietary information, including our trade secrets and know-how; and • the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us. Third-party manufacturers may not be able to comply with CGMP regulations or similar regulatory requirements outside the U. S. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Risks Related to Our Intellectual Property

Our success depends in large part on our ability to obtain and maintain patent protection in the U. S. and other countries with respect to our proprietary technology and products. We and our licensors have sought to protect our proprietary position by filing patent applications in the U. S. and abroad related to our novel technologies 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. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Maintaining patents in the U. S. is an expensive process and it is even more expensive to maintain patents and patent applications in foreign countries. As a result, it is possible that we and our licensors will fail to maintain such patents thereby reducing the rights of our portfolio. The patent position of pharmaceutical, biotechnology, and medical device companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, or which effectively prevent others from commercializing competitive technologies and products. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U. S. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U. S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability, and commercial value of our owned or licensed patent rights are highly uncertain. We currently have 39 pending patents. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional ~~pre-clinical~~ **preclinical** or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the U. S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U. S. Patent and Trademark Office, 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 products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products 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 current or future product candidates. Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. 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 U. S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate 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 products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringed their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly, or 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 proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. 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. Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market, and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the medical device, biotechnology, and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or

litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the U. S. Patent and Trademark Office. The risks of being involved in such litigation and proceedings may increase as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We may not be aware of all such intellectual property rights potentially relating to our product candidates and their uses. Thus, we do not know with certainty that KIO- 104, KIO- 301, or any other product candidate, or our commercialization thereof, does not and will not infringe or otherwise violate any third party' s intellectual property. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. 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. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business. We are party to licensing agreements that impose, and for a variety of purposes, we will likely enter into additional licensing and funding arrangements with third parties that may impose, diligence, development, and commercialization timelines and milestone payment, royalty, insurance, and other obligations on us. Under certain of our existing licensing agreements, we are obligated to pay royalties or make specified milestone payments on net product sales to the extent they are covered by the agreements. We also are obligated under certain of our existing license agreements to pay maintenance and other fees. We also have diligence and development obligations under certain of those agreements that we are required to satisfy. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture, or market any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property. Some of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. Litigation may be necessary to defend against these claims. In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self- executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management. Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for some of our technology and 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 these 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, and we may not be able to obtain adequate remedies for 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 U. S. are less willing or unwilling to protect trade secrets. 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. Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters If we are not able to obtain required regulatory approvals, we will not be able to commercialize KIO- 104, KIO- 301, or any other product candidate that we may develop, and our ability to generate revenue will be materially impaired. The marketing approval process is expensive, time- consuming, and uncertain. As a result, we cannot predict when or if we, or any collaborators we may have in the future, will obtain marketing approval to commercialize KIO- 104, KIO- 301, or any other product candidate. The activities associated with the development and commercialization of our product candidates, including KIO- 104 and KIO- 301, including design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the U. S. and similar regulatory authorities outside the U. S. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market KIO- 104, KIO- 301, or any other product candidate from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third- party CROs and consultants to assist us in this process. The process of obtaining marketing approvals, both in the U. S. and abroad, is expensive and may take many years, especially if additional clinical trials are required, if approval is obtained at all. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety, purity, and potency. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that KIO- 104, KIO- 301, or any other product candidate that we may develop is not safe, effective or pure, is only moderately effective or has undesirable or unintended side effects, toxicities, or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. The regulatory process can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad. In order to market and sell KIO- 104, KIO- 301, and any other product candidate that we may develop in other jurisdictions, we or our third- party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U. S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U. S., it is required that the product be approved for reimbursement before the product can be sold in that country. We or these third parties may not obtain approvals from regulatory authorities outside the U. S. on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U. S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. Even if we, or any collaborators that we have now or may have in the future, obtain marketing approvals for KIO- 104, KIO- 301, or our other product candidates, the terms of those approvals, ongoing regulations and post- marketing restrictions may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue. Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any collaborators that we have now or may have in the future, must therefore comply with requirements concerning advertising and promotion for any of our products for which we or they obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved labeling. Thus, if KIO- 104, KIO- 301, or any other product candidate that we may develop receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to CGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, our current and future collaborators, and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post- marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to physicians, recordkeeping, and costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product, such as the requirement to implement a risk evaluation and mitigation strategy. We may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion or manufacturing of prescription products may lead to investigations by the FDA, Department of Justice, and state Attorneys General alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various adverse results, including: • restrictions on such products, manufacturers, or manufacturing processes; • restrictions on the labeling or marketing of a product; • restrictions on product distribution or use; • requirements to conduct post- marketing studies or clinical trials; • warning letters; • withdrawal of the products from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products; • fines, restitution, or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • refusal to permit the import or export of our products;

• product seizure; or • injunctions or the imposition of civil or criminal penalties. Our relationships with customers and third-party payors may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings. Healthcare providers, physicians, and third-party payors in the U. S. and elsewhere will play a primary role in the recommendation and prescription of any product candidates, including KIO- 104 and KIO- 301, for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U. S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state, and foreign healthcare laws and regulations that may affect our ability to operate include: • the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; • federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which imposes obligations, including mandatory contractual terms, on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information; and • analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign 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 or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. 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, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be subject to criminal, civil, or administrative sanctions, including exclusions from participation in government funded healthcare programs. Previously enacted and future legislation may affect our ability to commercialize and the prices we obtain for any products that are approved in the U. S. or foreign jurisdictions. In the U. S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could affect our ability to profitably sell or commercialize any product candidate, including KIO- 104 and KIO- 301, for which we obtain marketing approval or that we may in-license. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Current laws, as well as 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 product. In the U. S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit coverage of and reduce the price that we receive for any approved products. While the MMA applies only to product benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA or other healthcare reform measures may result in a similar reduction in payments from private payors. In March 2010, former President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively "PPACA"). Among the provisions of PPACA of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, are the following: • an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; • an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; • a new Medicare Part D coverage gap discount program, in which participating manufacturers must agree to offer 50% point-of-sale discounts off negotiated drug prices during the coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; • expansion of healthcare fraud and

abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, and the addition of new government investigative powers, and enhanced penalties for noncompliance; • extension of manufacturers' Medicaid rebate liability; • expansion of eligibility criteria for Medicaid programs; and • expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program. In addition, other legislative changes have been proposed and adopted since PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, which went into effect in April 2013, and will remain in effect through 2030 unless additional Congressional action is taken. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding. In addition, it is possible that changes in administration and policy could result in additional proposals and / or changes to health care system legislation. Additionally, in light of the rising cost of prescription drugs and biologics, there has been heightened governmental scrutiny in the U. S. of pharmaceutical pricing practices. Such scrutiny has resulted in several recent 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 products. At both the federal and state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. In some cases, the legislation and regulations are designed to encourage importation from other countries and bulk purchasing. We expect that these, and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private 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 drugs. The pricing of prescription pharmaceuticals is also subject to governmental control outside the U. S. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired. If we or our third-party manufacturers fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur significant costs. We and our third-party manufacturers are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions. Further, with respect to the operations of our third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health, and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm, or experience a disruption in the manufacture and supply of our product candidates or products.

Risks Related to Employee Matters and Managing Growth We are highly dependent on the research and development, clinical, and business development expertise of Brian M. Strem, our Chief Executive Officer, **Eric Daniels, our Chief Development Officer, Melissa Tosca, our Chief Financial Officer,** as well as the other principal members of our management, scientific, and clinical team and a number of third-party consultants. Although we have entered into ~~an~~ employment ~~agreement~~ **agreements** with Dr. Strem, ~~he~~ **Dr. Daniels and Ms. Tosca, they** may terminate ~~his~~ **their** employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize products. 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. The availability of qualified personnel in the markets in which we operate has declined in recent years and competition for such labor has increased. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have

commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. We expect to expand our development capabilities and potentially implement sales, marketing, and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. We may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing, and distribution. To manage our potential 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 potential growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. We may fail to realize any benefits and incur losses related to any acquisition. We regularly explore opportunities to grow our business, including through acquiring companies. The success of our strategic acquisitions will depend, in part, on our ability to successfully integrate the acquired businesses with our existing business. It is possible that the integration process could result in the loss of key employees; the disruption of ongoing business; or inconsistencies in standards, controls, procedures, and policies that adversely affect our ability to maintain relationships with vendors, customers, and employees or to achieve the anticipated benefits of the acquisition. Successful integration may also be hampered by any differences between the operations and corporate culture of the two organizations. If we experience difficulties with the integration process, the anticipated benefits of the acquisition may not be realized fully, or at all, or may take longer to realize than expected.

Risks Related to Our Common Stock We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, any future debt agreements that we may enter into, may preclude us from paying dividends without the lenders' consent or at all. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. **The We could face delisting from Nasdaq in the event we do not meeting its minimum bid price of rules. On July 18, 2023, we received a written notification (the " Notice Letter ") from Nasdaq indicating that we were not in compliance with Nasdaq Listing Rule 5550 (a) (2), as the closing bid price for our common stock was below the \$ 1. 00 per share requirement may be volatile and fluctuate substantially, which could result in substantial losses for purchasers the last 30 consecutive business days. The Notice Letter stated that we have 180 calendar days, or until January 15, 2024 (the " Initial Compliance Period "), to regain compliance with the minimum bid price requirement. To regain compliance with the minimum bid price requirement, the closing bid price of our common stock must be at least \$ 1. 00 per share. Our common stock is thinly traded and hence the price may be volatile. The stock market in general and the market for smaller specialty pharmaceutical companies a minimum of 10 consecutive trading days during this 180- day compliance period, unless the Nasdaq staff exercises its discretion to extend this period pursuant to Nasdaq Listing Rule 5810 (e) (3) (H). On January 16, 2024, Nasdaq notified us in particular, have experienced extreme volatility writing (the " Extension Letter ") that while we had not regained compliance with the Bid Price Rule, we were eligible for an additional 180- day compliance period, or until July 15, 2024, to regain compliance with the Bid Price Rule. Nasdaq' s determination was based on our having met the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on The Nasdaq Capital Market, with the exception of the Bid Price Rule, and on our written notice to Nasdaq of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. In the event that we do not regain compliance with Listing Rule 5550 (a) (2) prior to the expiration of the compliance period, we will receive written notification that our securities are subject to delisting. At that time, we may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. A delisting of our Common Stock would have an adverse effect on the market liquidity of our Common Stock and, as has often been unrelated to the operating performance of particular companies. As a result of this volatility , you may not be able to sell your common stock at or above the price you paid for such shares. The market price for our Common Stock could become more volatile. Further, a delisting also could make it more difficult for us to raise additional capital. We intend to monitor the closing bid price of our common stock and may be influenced by may many conduct factors, including:**

- the success of competitive products or technologies;
- the results of clinical trials of KIO- 104, KIO- 301, or any other product candidate that we may develop;
- the results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire, or in- license additional products, product candidates, or technologies for the treatment of ophthalmic diseases, the costs of commercializing any such products, and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- reduction in stock price could indicate impairment of the goodwill and intangible assets;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions; and
- the other factors described in this " Risk Factors " section.

In the past, following periods of volatility in the market price of a company a reverse stock split company' s securities , securities class- action litigation has often been instituted against that company. We also may face securities class- action litigation if necessary, we cannot obtain regulatory approvals for or if we otherwise fail to regain compliance with the Nasdaq bid price rule commercialize KIO- 104 or KIO- 301. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management' s attention and resources .

General Risk Factors Laws and regulations governing international operations may preclude us from developing, manufacturing, and selling certain products outside of the U. S. and require us to develop and implement costly compliance programs. We must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate, including our operations in Australia and Austria. The Foreign Corrupt Practices Act ("FCPA") prohibits any U. S. individual or business from paying, offering, authorizing payment, or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U. S. to comply with certain accounting provisions requiring the Company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations, and executive orders also restrict the use and dissemination outside of the U. S., or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our foreign operations require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U. S., which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA's accounting provisions. Our business and operations would suffer in the event of system failures. Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, 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 restated certificate of incorporation and our amended and restated bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also 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 only one of three classes of directors is elected each year; • 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 our board of directors; • 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 effected 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 "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 affirmative vote of stockholders holding at least two-thirds of shares entitled to be cast to amend or repeal specified provisions of our restated certificate of incorporation or our amended and restated bylaws. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. The price of our common stock may..... management's attention and resources. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. As of December 31, ~~2023~~ **2024**, we had federal net operating loss carryforwards of approximately \$ ~~90.31~~ **2.7** million, ~~no~~ state net operating loss carryforwards of approximately \$ ~~63.6~~ million, and ~~aggregate~~ **no** federal and state research and development tax credit carryforwards of approximately \$ ~~2.5~~ million and \$ ~~0.5~~ million, respectively, available to reduce future taxable income. ~~Certain of these~~ **These** federal and state net operating loss carryforwards **are from** and federal and state tax credit carryforwards will expire at various dates through 2042, if not utilized. ~~Federal net operating losses generated as of December 31, 2017 and prior, will carry forward until 2037 and~~ net operating losses generated during the year ended December 31, 2018 and later, **and as such** will be carried forward indefinitely until utilized, but their utilization will be limited to 80 % of taxable income. Utilization of these net operating loss and tax credit carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and comparable provisions of state, local, and foreign tax laws due to changes in ownership of our company that have occurred

previously or that could occur in the future. Under Section 382 of the Code and comparable provisions of state, local, and foreign tax laws, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 % change by value in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research and development tax credits, to reduce its post-change income may be limited. ~~We have not~~ **In 2024, we** completed a study to determine whether our initial public offering, subsequent public and private offerings, and other transactions that have occurred may have triggered an ownership change limitation. **The analysis determined that ownership changes (under the definition of Section 382) occurred in multiple years. The base limitation calculated for these changes ranged from \$ 170, 643 to \$ 494, 650. In addition to the annual NOL limitation, we had a Net Unrealized Built- In Loss (NUBIL) on the date of the ownership changes in multiple years. The total NUBIL was \$ 17, 519, 701. As a result of the NUBIL, we adjusted our Federal NOL carryforwards for the 2018 through 2022 tax years down by a total of \$ 9, 126, 676 in total with the filing of our 2023 tax return. Additionally, \$ 3, 146, 111 of the NUBIL was recognized as an unfavorable book to tax adjustment during the 2023 tax year. The remaining NUBIL will be recognized in tax years 2024 and 2025.** We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we generate taxable income, our ability to use our pre-change net operating loss and tax credits carryforwards to reduce U. S. federal and state taxable income may be subject to limitations, which could result in increased future tax liability to us. In addition, the Tax Cuts and Jobs Act (TCJA) enacted on December 22, 2017, limits the amount of net operating losses that we are permitted to deduct in any taxable year to 80 % of our taxable income in such year. The TCJA also eliminates the ability to carry back net operating losses to prior years, but allows net operating losses generated after 2017 to be carried forward indefinitely. As such, there is a risk that due to such items, our existing net operating losses could expire or be unavailable to offset future income. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities. We are a smaller reporting company and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors. We are a smaller reporting company (“SRC”) and a non-accelerated filer, which allows us to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not SRCs or non-accelerated filers, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, as amended, reduced disclosure obligations, including disclosures regarding executive compensation, in our Annual Report and our periodic reports and proxy statements and providing only two years of audited consolidated financial statements in our Annual Report and our periodic reports. We will remain an SRC until (a) **in the event we have more than \$ 100 million in annual revenues,** the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds \$ 250 million or (b) in the event we have ~~over less than~~ **\$ 100 million in annual revenues,** the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds \$ 700 million. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and may decline. As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, Financial Industry Regulatory Authority (“FINRA”) rules, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. We continue to evaluate these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Pursuant to Section 404 of the Sarbanes- Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain a non-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. To achieve compliance with Section 404 within the prescribed period, we have engaged in a process to document and evaluate our internal control over financial reporting. In this regard, we will need to continue to dedicate internal resources, engage outside consultants, and adopt a detailed work plan to continue to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements. A material amount of our assets represents intangible assets, and our net income would be reduced if our intangible assets become impaired. As of December 31, ~~2023-2024~~, intangible assets, net, represented approximately \$ ~~8-6~~ **8-7** million, or ~~64-18~~ % of our total assets. Indefinite-lived intangible assets are subject to an impairment analysis at least annually based on fair value. Intangible assets relate primarily to in-process research and development (“IPR & D”) and patents acquired by us as part of our acquisitions of other companies, and are subject to an impairment analysis whenever events or changes in circumstances

exist that indicate that the carrying value of the intangible asset might not be recoverable. If market and economic conditions or business performance deteriorate, the likelihood that we would record an impairment charge would increase, which impairment charge could materially and adversely affect our financial condition and operating results.