Risk Factors Comparison 2025-03-31 to 2024-03-29 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10- K, including our financial statements and the related notes appearing at the end of this Annual Report on Form 10- K, before deciding to invest in our common stock. These risks, some of which have occurred and any of which may occur in the future, can have a material adverse effect on our business, prospects, operating results and financial condition. In such event, the trading price of our common stock could decline and you might lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business, prospects, operating results and financial condition. Risks Related to Our Financial Position and Need for Additional Capital We have incurred significant losses from operations and negative cash flows from operations since our inception. We expect to incur additional losses and may never achieve or maintain profitability. Since inception, we have incurred significant losses from operations and negative cash flows from operations. Our net losses were $ **38. 5 million and $** 42. 2 ~~million and $ 44. 8~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~, respectively. As of December 31, ~~2023~~ **2024**, we had an accumulated deficit of $ ~~629~~ **667**. ~~4~~ **9** million. Prior to the sale of the rights to manufacture, sell, distribute, market and commercialize EYSUVIS and INVELTYS and to develop, manufacture, market and otherwise exploit the AMPPLIFY Drug Delivery Technology, which we collectively refer to as the Commercial Business, to Alcon Pharmaceuticals Ltd. and Alcon Vision, LLC, or collectively Alcon, in July 2022, we generated only limited revenues from sales of EYSUVIS and INVELTYS. We have financed our operations primarily through proceeds from the sale of our Commercial Business to Alcon in July 2022, our initial public offering, follow- on public offerings of common stock and sales under our at- the- market offering facilities, private placements of common stock and / or preferred stock **(including our most recent private placements of common stock and preferred stock for gross proceeds of approximately $ 8. 6 million in March 2024, $ 12. 5 million in June 2024 and $ 10. 8 million in December 2024)**, borrowings under credit facilities and the Loan and Security Agreement with Oxford Finance LLC, or the Loan Agreement, **disbursements under a grant from CIRM (including our most recent disbursements of $ 3. 2 million and $ 2. 5 million from CIRM in August 2024 and December 2024, respectively, upon achievement of specified milestones),** convertible promissory notes and warrants ~~. Upon entry into the CIRM award in August 2023, Combangio received an initial $ 5. 9 million disbursement from CIRM, and the balance of the $ 15. 0 million award is payable to Combangio upon the achievement of specified milestones~~. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials, and prior to the sale of our Commercial Business to Alcon in July 2022, engaging in activities to launch and commercialize EYSUVIS and INVELTYS. **We** ~~As a result of the acquisition of Combangio in November 2021 and the sale of our Commercial Business to Alcon, we~~ are devoting substantial financial resources to the research and development and potential commercialization of KPI- 012, our product candidate in clinical development for the treatment of persistent corneal epithelial defects, or PCED, and any other indications we determine to pursue, including Limbal Stem Cell Deficiency. We have no revenue- generating commercial products, our cash flows have diminished as a result of the sale of our Commercial Business to Alcon and, as a result of our acquisition of Combangio, we may be required to pay certain milestones and royalty payments to former equityholders of Combangio. Although we are eligible to receive up to $ 325. 0 million in payments from Alcon based upon the achievement of specified commercial sales- based milestones with respect to EYSUVIS and INVELTYS, there can be no assurance as to when we may receive such milestone payments or of the amount of milestone payments we may receive, if any. We also cannot assure you that we will achieve **the remaining** milestones **under** ~~within the timeframe required by~~ the CIRM award **within required timeframes**, or at all, and as such we may never receive the remaining $ ~~9~~ **3**. ~~1~~ **3** million under the award. We expect to continue to incur significant expenses and operating losses for the foreseeable future, including in connection with our continued development, regulatory approval efforts and commercialization, if any, of KPI- 012. We may never achieve or maintain profitability. Our net losses may fluctuate significantly from quarter- to- quarter and year- to- year. We anticipate that our research and development expenses will increase substantially in the future as compared to prior periods as we advance the clinical development of KPI- 012. Our research and development expenses will also increase in the future as we conduct any necessary preclinical studies and clinical trials and other development activities for any other product candidates we may develop in the future, including our planned preclinical studies under our KPI- 014 program, which is a mesenchymal secretome formulation that is in preclinical development for the treatment of inherited retinal degenerative diseases, such as Retinitis Pigmentosa and Stargardt Disease. If we obtain marketing approval for KPI- 012 or any product candidates we may develop, we expect that our ~~selling,~~ general and administrative expenses will increase substantially if and as we incur commercialization expenses related to product marketing, sales and distribution. Our expenses will also increase if and as we: ● continue the clinical development of KPI- 012 for PCED; ● initiate and continue the research and development of KPI- 012 for additional indications, such as Limbal Stem Cell Deficiency, including initiating and conducting preclinical studies and clinical trials; ● scale up our manufacturing processes and capabilities to manufacture the clinical supply of KPI- 012; ● seek regulatory approval for KPI- 012 for PCED in the United States and other jurisdictions; ● seek regulatory approval for KPI- 012 for additional indications; ● grow our sales, marketing and distribution capabilities in connection with the commercialization of any product candidates for which we may submit for and obtain marketing approval; ● initiate and progress any preclinical development programs under our mesenchymal stem cell secretome, or MSC- S platform, including from our KPI- 014 program;

● conduct clinical trials and other development activities and / or seek marketing approval for any product candidates we may develop in the future; ● in- license or acquire the rights to other products, product candidates or technologies; ● maintain, expand and protect our intellectual property portfolio; ● hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel to support our operations; ● expand our operational, financial and management systems; and ● increase our product liability insurance coverage if we initiate commercialization efforts for our product candidates. 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 from what we anticipate if: ● we elect or are required by the U. S. Food and Drug Administration, or FDA, or non- U. S. regulatory agencies to perform clinical trials or studies in addition to those expected; ● there are any delays in enrollment of patients in or completing our clinical trials or the development of our product candidates; ● we in- license or acquire rights to other products, product candidates or technologies; or ● there are any third- party challenges to our intellectual property portfolio, or the need arises to defend against intellectual property- related claims or enforce our intellectual property rights. ~~47Our~~ **50Our** ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate revenue from KPI- 012 or any other product candidate we may develop for the foreseeable future, if at all. Achieving and maintaining profitability will require us to be successful in a range of challenging activities, including: ● completing the clinical development of KPI- 012 for PCED and any other indications we determine to pursue, including Limbal Stem Cell Deficiency; ● subject to obtaining favorable results from our ongoing and planned clinical trials of KPI- 012, applying for and obtaining marketing approval of KPI- 012; ● successfully commercializing KPI- 012, if approved; ● discovering, developing and successfully seeking marketing approval and commercialization of any additional product candidates we may develop in the future, including under our KPI- 014 program; ● hiring and building a full commercial organization required for marketing, selling and distributing those products for which we obtain marketing approval; ● manufacturing at commercial scale, marketing, selling and distributing those products for which we obtain marketing approval; ● achieving an adequate level of market acceptance, and obtaining and maintaining coverage and adequate reimbursement from third- party payors for any products we commercialize; and ● obtaining, maintaining and protecting our intellectual property rights. As a company, we have limited experience commercializing products, and we may not be able to commercialize a product successfully in the future. There are numerous examples of unsuccessful product launches and failures to meet expectations of market potential, including by pharmaceutical companies with more experience and resources than us. We may never succeed in the foregoing activities and we may never generate revenue that is sufficient to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of 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. Our limited operating history and our limited..... as indications of future operating performance. 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 efforts **or cease operations** . We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct research and development activities, and initiate **and conduct** clinical trials of, and seek regulatory approval for, KPI- 012 and any other product candidate that we develop in the future. If we do obtain regulatory approval for KPI- 012 or any other product candidate that we develop, we expect to incur commercialization expenses related to product sales, marketing, distribution and manufacturing capabilities. 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 **or cease operations and, potentially, wind down the company under the bankruptcy laws or otherwise** . **If we were to cease operations and wind down the company under the bankruptcy laws or otherwise, we cannot assure our stockholders or other stakeholders of any specific level of recovery, or any recovery at all on their specific claims or interest.** ~~Our~~ **51Our** future capital requirements will depend on many factors, including: ● the timing and amount of milestone payments we ultimately receive from Alcon under the asset purchase agreement; ● the timing and amount of our future milestone payments to Combangio equityholders under the merger agreement; ● the timing and amount of milestone payments we ultimately receive from CIRM in connection with the CIRM Award; ● the progress, costs and results of our ongoing and planned clinical trials of KPI- 012; ● the costs and timing of process development and manufacturing scale- up activities associated with KPI- 012 for PCED and any other indications we determine to pursue; ● the costs, timing and outcome of regulatory review of KPI- 012; ● the costs and timing of commercialization activities for KPI- 012, if approved, including establishing and / or expanding product sales, marketing, medical affairs, distribution and outsourced manufacturing capabilities; ● our ability to successfully commercialize KPI- 012, if approved, in the United States and other jurisdictions and the amount of revenue received from commercial sales; ● our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements; ● the scope, progress, results and costs of research and development of any other product candidates that we may develop, including under our KPI- 014 program; ● the extent to which we successfully advance and / or in- license or acquire rights to other products, product candidates or technologies; and ● the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property- related claims. We expect to continue to incur significant expenses and operating losses. Net losses may fluctuate significantly from quarter- to- quarter and year- to- year. We expect that our cash and cash equivalents of $ ~~50~~ **51** . ~~9~~ **2** million as of December 31, ~~2023, together with the $ 8. 6 million of gross proceeds we received from the sale of shares of our preferred stock in a private placement in March~~ 2024 ~~and the $ 9. 1 million of remaining funding anticipated under the CIRM Award,~~ will enable us to fund our operations, lease and debt service obligations and capital expenditure requirements into the ~~third~~ **first** quarter of ~~2025~~ **2026** .

We expect that our existing cash resources will be sufficient to enable us to obtain **topline** safety and efficacy data from our ongoing CHASE Phase 2b clinical trial of KPI- 012 in PCED. However, we do not expect that our existing cash resources will be sufficient to enable us to complete the clinical development of KPI- 012 for PCED or for any other indication. We have based our estimates on assumptions that may prove to be wrong, and our operating plan may change ~~49as~~ **as** a result of many factors currently unknown to us. For example, **our estimates assume that** we ~~may~~ **remain in compliance with the covenants and** ~~not~~ - **no event** ~~receive all~~ of **default occurs** ~~the funds awarded~~ under **our Loan Agreement with Oxford Finance. If an event of default occurs under our Loan Agreement and Oxford Finance exercises its rights under** the ~~CIRM Award~~ **Loan Agreement to foreclose on our cash, our ability to fund our operations, lease and debt service obligations will be shorter than we currently expect** . As a result, we could deplete our available capital resources sooner than we currently expect. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. We may never generate the necessary data or results required to obtain marketing approval and achieve product sales from KPI- 012 or any other product candidate we ~~develop~~ **52develop** . Also, even if we successfully develop KPI- 012 or any other product candidate and one or more of those are approved, we may not achieve commercial success with them. Accordingly, we will require additional financing to achieve our business objectives. In addition, we may opportunistically raise 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. Adequate additional financing may not be available to us on acceptable terms, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize any product candidate for which we obtain approval. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. 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, collaborations, strategic alliances, licensing arrangements, royalty agreements, and marketing and distribution arrangements. 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 rights and preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include pledging of assets as collateral and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For example, our pledge of our assets as collateral to secure our obligations under our Loan Agreement may limit our ability to obtain additional debt financing. Under the Loan Agreement, we are also restricted from paying dividends on our common stock, granting liens, making investments, making acquisitions, making certain restricted payments, selling assets and making certain other uses of our cash without the lenders' consent, subject in each case to certain exceptions. In addition, under our securities purchase agreements for our 2022, 2023 and 2024 private placements, we have agreed that we will not, without the prior approval of the **applicable** requisite purchasers **under such purchase agreements** : (1) issue or authorize the issuance of any equity security that is senior or pari passu to the Series E ~~Convertible Non- Redeemable~~ Preferred Stock, the Series F ~~Convertible Non- Redeemable~~ Preferred Stock ~~or~~ **,** the Series G ~~Convertible Non- Redeemable~~ **Preferred Stock, the Series H Preferred Stock and the Series I** Preferred Stock with respect to liquidation preference, (2) incur any additional indebtedness for borrowed money in excess of $ 1. 0 million, in the aggregate, outside the ordinary course of business, subject to specified exceptions, including the refinancing of its existing indebtedness or (3) pay or declare any dividend or make any distribution on, any of our shares of capital stock, subject to specified exceptions. In addition, if we raise additional funds through collaborations, strategic alliances, licensing arrangements, royalty agreements, 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 current 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 **or cease operations and, potentially, wind down the company under the bankruptcy laws or otherwise. If we were to cease operations and wind down the company under the bankruptcy laws or otherwise, we cannot assure our stockholders or other stakeholders of any specific level of recovery, or any recovery at all on their specific claims or interest** . Our substantial indebtedness may limit cash flow available to invest in the ongoing needs of our business and a failure to comply with the covenants under our Loan Agreement, such as the requirement that our common stock continue to be listed on The Nasdaq Stock Market, **or to avoid the occurrence of specified events of default** could result in an ~~event of default and~~ acceleration of amounts due. We have a substantial amount of indebtedness. As of December 31, ~~2023~~ **2024** , we had $ ~~34~~ **29** . ~~0~~ **3** million of outstanding borrowings under the tranche A term loan under the Loan Agreement, which through June 30, 2023 bore interest at a ~~50floating~~ -- **floating** rate equal to the greater of 30- day LIBOR and 0. 11 %, plus 7. 89 %. Effective July 1, 2023, the term loan bears interest at a floating rate equal to the greater of (i) 8. 00 % and (ii) the sum of (a) the 1- Month CME Term Secured Overnight Financing Rate, ~~or SOFR,~~ (b) 0. 10 % and (c) 7. 89 %. Fluctuations in interest rates could materially affect the interest expense on our Loan Agreement. The start date for amortization payments under the Loan Agreement is ~~January~~ **July** 1, 2025, at ~~which~~ **53which** time the aggregate principal balance of the term loan then outstanding under the Loan Agreement is required to be repaid in monthly installments through ~~May~~ **November** 1, 2026. Pursuant to the Loan Agreement, we may also make partial prepayments of the term loan to the lender, subject to specified conditions, including the payment of applicable fees and accrued and unpaid interest on the principal amount of the term loan being repaid. Our obligations under the Loan Agreement are secured by substantially all of our assets. Our debt combined with our other financial obligations and

contractual commitments could have significant adverse consequences, including: ● requiring us to dedicate a substantial portion of cash flow from operations or cash on hand to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes; ● increasing our vulnerability to adverse changes in general economic, industry and market conditions; ● subjecting us to restrictive covenants that may reduce our ability to acquire other businesses for cash, take certain other corporate actions or obtain further debt or equity financing; ● limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and ● placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options. We may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt, particularly if we are in default under our Loan Agreement and all of our indebtedness under the Loan Agreement is due, and funds from external sources may not be available on a timely basis or acceptable terms, if at all. In addition, a failure to comply with the covenants under our Loan Agreement could result in an event of default and acceleration of amounts due. In particular, a delisting of our common stock from The Nasdaq Capital Market or a transfer of the listing of our common stock to another nationally recognized stock exchange having listing standards that are less restrictive than The Nasdaq Capital Market, in each case after a specified cure period, are events of default under our Loan Agreement. **Our lender could also declare a default upon the occurrence of any event that is determined to be a material adverse change as defined under our Loan Agreement.** In such ~~event~~ **events** , we may not be able to make accelerated payments, and the lender could seek to enforce security interests in the collateral securing such indebtedness **, including by foreclosing on our cash, potentially requiring us to renegotiate our agreement on terms less favorable to us, or to immediately cease operations** . Acceleration of the repayment of the outstanding indebtedness would raise substantial doubt about our ability to continue as a going concern, shorten the period for which we will be able to fund our operations and capital expenditure requirements ~~and~~ **,** would adversely effect our financial condition and ability to pursue our business strategy **and may cause us to cease operations and seek protection and wind down the company under the bankruptcy laws or otherwise** . **For more information about risks related to compliance with The Nasdaq Capital Market listing standards, please see " Risks Related to Our Common Stock- If we fail to comply with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. If our common stock is delisted from Nasdaq, we will be in default under our Loan Agreement. "** The milestone consideration we are eligible to receive in connection with the sale of our Commercial Business to Alcon is subject to various risks and uncertainties. The milestone consideration we are eligible to receive for the sale of our Commercial Business to Alcon is subject to various risks and uncertainties. **We** ~~In addition to the upfront payment of $ 60. 0 million we received from Alcon at closing, we~~ are eligible to receive up to four commercial- based sales milestone payments **from Alcon** as follows: (1) $ 25. 0 million upon the achievement of $ 50. 0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (2) $ 65. 0 million upon the achievement of $ 100. 0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (3) $ 75. 0 million upon the achievement of $ 175. 0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029 and (4) $ 160. 0 million upon the achievement of $ 250. 0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029. ~~We~~ **To date, we have not received any such milestone payments. 54We** cannot predict what success, if any, Alcon and its affiliates may have with respect to sales of EYSUVIS and INVELTYS and, therefore, it is uncertain as to when we may receive the milestone payments, which milestone payments we may receive and if we will receive any milestone payments at all. If we do not receive some or all of the milestone payments, our business will be harmed. ~~51If~~ **If** our estimates or judgments relating to our critical accounting policies, or any of our projections, prove to be inaccurate or financial reporting standards or interpretations change, our results of operations could be adversely affected. The preparation of financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities and expenses. Such estimates and judgments include the present value of lease liabilities and the corresponding right- of- use assets, the fair value of warrants, stock- based compensation, accrued expenses, contingent consideration, grant income and deferred grant income, the valuation of embedded derivatives and the recoverability of our net deferred tax assets and related valuation allowance. We base our estimates and judgments on historical experience, expected future experience and on various other assumptions that we believe to be reasonable under the circumstances. In addition, from time to time, we may rely on projections regarding our expected future performance that represent our management' s then- current estimates. However, any of these estimates, judgments or projections, or the assumptions underlying them, may change over time or may otherwise prove to be inaccurate ~~. In particular, to report historical product revenue, we estimated the amount of our products that may be returned and presented this amount as a reduction of revenue in the period the related product revenue was recognized, in addition to establishing a liability. If our product return estimates are lower than the actual amount of product returns we experience, our existing reserves will be insufficient to cover future returns~~ . Our results of operations may be adversely affected if our estimates, assumptions or projections change or if actual circumstances differ from those in our estimates or assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the trading price of our common stock. Additionally, we regularly monitor our compliance with applicable financial reporting standards and review new pronouncements and drafts thereof that are relevant to us. As a result of new standards, changes to existing standards and changes in their interpretation, we might be required to change our accounting policies, alter our operational policies and implement new or enhance existing systems so that they reflect new or amended financial reporting standards, or we may be required to restate our published financial statements. Such changes to existing standards or changes in their interpretation may have an adverse effect on our

reputation, business, financial position and results of operations. Our limited operating history and our limited experience in developing biologics may make it difficult for you to evaluate the success of our business to date and to assess our future viability.Our operations to date have been limited to organizing and staffing our company,acquiring rights to intellectual property,business planning,raising capital,conducting research and development activities,and prior to the sale of our Commercial Business to Alcon in July 2022,developing and commercially launching EYSUVIS and INVELTYS.While we have had experience with obtaining marketing approval for and commercially launching two commercial products,we no longer have any commercial products following the sale of our Commercial Business to Alcon,we have only one product candidate in clinical development and we cannot be certain that we will be able to develop,obtain marketing approval for and commercialize a product in the future.If we are successful in developing and obtaining marketing approval for KPI- 012 or any product candidate we may develop in the future,we will again have to transition from a company with a research and development focus to a company capable of supporting commercial activity.We may not be successful in such a transition.In addition,prior to our acquisition of KPI- 012 in November 2021,we had no prior experience developing biological product candidates.As such,we may encounter delays or difficulties in our efforts to develop and commercialize KPI- 012.Consequently,any predictions you make about our future success or viability may not be as accurate as they could be if we had prior experience developing biological product candidates or a longer operating and commercialization history. ~~We~~ **48We** expect our financial condition and operating results 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. ~~Risks~~ **55Risks** Related to Product Development We are substantially dependent on the success of our product candidate, KPI- 012. If we are unable to successfully complete the clinical development of, and obtain marketing approval for, KPI- 012 or any other product candidate we may develop in the future, or experience significant delays in doing so, or if, after obtaining marketing approvals, we fail to successfully commercialize such product candidates, our business will be materially harmed. We are substantially dependent on the success of KPI- 012 and any other product candidate we may develop in the future. As a result, we intend to devote a substantial portion of our research and development resources and business efforts to the development of KPI- 012. The success of KPI- 012 and any other product candidates we may develop in the future will depend on many factors, including the following: ● completing and obtaining favorable results from our ongoing and planned clinical trials of KPI- 012 and any other product candidate we develop; ● clearance of any investigational new drug application, or IND, submission for any other product candidates we develop; ● applying for and receiving marketing approvals from the FDA and any other regulatory authorities for KPI- 012 and any other product candidate we develop; ● if approved, successfully launching and commercializing KPI- 012 or any other product candidate we develop in the United States, including establishing and maintaining sales, marketing, manufacturing and distribution capabilities for KPI- 012 or any other product candidate we develop; ~~52~~ ● if approved, obtaining acceptance of KPI- 012 and any other product candidate we develop by patients, the medical community and third- party payors; ● obtaining and maintaining coverage, adequate pricing, and adequate reimbursement from third- party payors, including government payors, for our product candidates; ● obtaining and maintaining regulatory approval of our manufacturing processes and our third- party manufacturers' facilities from applicable regulatory authorities and obtaining and maintaining adequate supply of any such approved products; ● maintaining a workforce of experienced scientists and others with experience in eye diseases and biologics to continue to develop our product candidates; ● effectively competing with other therapies; ● maintaining an acceptable potency, purity and safety profile of our products following approval; ● obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates; ● protecting our rights in our intellectual property portfolio; and ● not infringing, misappropriating or otherwise violating others' intellectual property rights. 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 KPI- 012 or any other product candidate we may develop in the future, which would materially harm our business. We may never generate the necessary data or results required to ~~obtain~~ **56obtain** regulatory approval of KPI- 012 or any other product candidate we develop and the commercialization of KPI- 012 or any other product candidate we develop may never occur. If clinical trials of KPI- 012 or any other biological product candidate that we develop fail to demonstrate potency, safety and purity to the satisfaction of the FDA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate. The risk of failure in developing product candidates is high. It is impossible to predict when or if any product candidate would prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the potency, purity and safety for a biologic product 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 stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, the results of Combangio' s Phase 1b clinical trial of KPI- 012 in twelve patients, including nine with PCED, may not be indicative of future results in later stage clinical trials, including in our ongoing CHASE Phase 2b clinical trial of KPI- 012 in patients with PCED. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Furthermore, the failure of any product candidates to demonstrate potency, safety and purity in any clinical trial could negatively impact the perception of our other product candidates and / or cause the FDA or other regulatory authorities to require additional testing before approving any of our product candidates. For example, in our STRIDE 2 Phase 3 clinical trial evaluating the safety and efficacy of EYSUVIS versus placebo in patients with dry eye disease, we did not achieve statistical significance for the primary symptom endpoint of ocular discomfort severity, and

subsequently we received a complete response letter from the FDA indicating that positive efficacy data from an additional clinical trial was needed to support a new drug application for EYSUVIS. ~~53If~~ **If** we are required to conduct additional clinical trials or other testing of KPI- 012 or any other product candidate we develop beyond those that we currently expect, 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 positive or are only modestly positive 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, including boxed warnings; ● be subject to additional post- marketing testing requirements; or ● have the product removed from the market after obtaining marketing approval. ~~If~~ **57If** 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, and our competitors could bring products to market before we do. 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 KPI- 012 or any other product candidate that we may develop, including: ● clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may recommend or 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; ● our third- party contractors may fail to comply with regulatory requirements or meet their 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; ● we may be subject to additional post- marketing testing requirements to maintain regulatory approval; ● regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; ● 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 or may be delayed; ● 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 trials; ● restrictions resulting from health epidemics, including COVID- 19, and their collateral consequences may result in internal and external operational delays and limitations; ~~and54 --~~ **and** ● regulatory authorities may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a modified Risk Evaluation and Mitigation Strategy, or REMS. 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 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, such as those developing treatments for PCED, to bring products to market before we do and impair our ability to successfully commercialize our product candidates. ~~If~~ **58If** 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 KPI- 012 or any other product candidate 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 United States. Patient enrollment is affected by a variety of factors, including: ● the prevalence and severity of the disease or condition under investigation; ● the patient eligibility criteria for the trial in question; ● the perceived risks and benefits of the product candidate under study; ● the existence of existing treatments for the indications for which we are conducting clinical trials; ● the efforts to facilitate timely enrollment in clinical trials; ● the patient referral practices of clinicians; ● the ability to monitor patients adequately during and after treatment; ● the proximity and availability of clinical trial sites for prospective patients; ● the conducting of clinical trials by competitors for product candidates that treat the same indications as our product candidates; ● the impact of public health epidemics, such as COVID- 19; and ● the lack of adequate compensation for prospective patients. We are developing KPI- 012 for PCED, which is a rare condition with an estimated incidence in the United States of 100, 000 cases per year, and, ~~as such,~~ we **have in the past and** may **in the future** have difficulty identifying and enrolling a sufficient number of patients in our ~~ongoing and planned~~ clinical trials of KPI- 012 given the limited number of patients with PCED. Our inability to locate and enroll a sufficient number of patients for our clinical trials could result in significant delays, could **cause us to reduce the number of patients that we enroll in a trial, 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 **have in the past and** may **in the future** 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. ~~55If~~ **59If** serious adverse or unacceptable side effects are identified during the development or commercialization of our product candidates, we may need to abandon or limit our development and / or commercialization efforts for such product candidates. If KPI- 012 or any other product candidate we develop are associated with serious adverse events or undesirable side effects in clinical trials or following approval and / or commercialization, or if any of our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development or marketing to narrower 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. While KPI- 012 was generally well- tolerated in Combangio' s Phase 1b clinical trial, it was only administered in 12 subjects. Compounds that initially show promise in clinical or earlier stage testing for treating eye disease or other diseases may later be found to cause

side effects that prevent further development and commercialization of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later, even following approval and / or commercialization, be found to be caused by the study treatment. Moreover, incorrect or improper use of a product by patients could result in additional unexpected side effects or adverse events. There can be no assurance that any product we may develop will be used correctly, and if used incorrectly, such misuse could hamper commercial adoption or market acceptance of such products or product candidates, if approved, at the rate we currently expect. 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. In July 2022, we sold our Commercial Business, including EYSUVIS and INVELTYS, to Alcon and we made a strategic determination to cease the development of our preclinical pipeline programs that are unrelated to our MSC- S platform and to focus our research and development efforts solely on this platform. We may never realize the anticipated benefits of these decisions and, as a result, we may be required to forego or delay other opportunities. In addition, 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 KPI- 012 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. KPI- 012 has been evaluated in a clinical trial outside of the United States and we may in the future conduct clinical trials for product candidates at sites outside the United States. The FDA may not accept data from trials conducted in such locations. ~~Combangio has in the past chosen, and we may in the future choose, to conduct one or more of our clinical trials outside the United States, including adding sites in Latin America for the CHASE Phase 2b clinical trial, subject to regulatory approval.~~ Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to conditions imposed by the FDA. For example, where data from foreign clinical trials are not intended to serve as the sole basis for approval in the United States, the FDA will not accept the data as support for a marketing application unless the clinical trial was well designed and conducted in accordance with **good clinical practices, or** GCP requirements. The FDA must also be able to validate the data from the trial through an onsite inspection, if necessary. In addition, these clinical trials are subject to the applicable local laws of the jurisdictions where the trials are conducted. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates. In addition, conducting clinical trials outside the United States could have a significant adverse impact on us. Risks inherent in conducting international clinical trials include: clinical practice patterns and standards of care that vary ~~56widely~~ -- **widely** among countries; non- U. S. regulatory authority requirements that could restrict or limit our ability to conduct our clinical trials; compliance with foreign manufacturing, customs, shipment and storage requirements; administrative ~~burdens~~ **60burdens** of conducting clinical trials under multiple non- U. S. regulatory authority schema; foreign exchange fluctuations; diminished protection of intellectual property in some countries; and interruptions or delays resulting from geopolitical events, such as wars. In 2020 and 2021, Combangio conducted a Phase 1b clinical trial of KPI- 012 in nine patients with PCED in Mexico. Based on the results of the Phase 1b clinical trial conducted in Mexico, we initiated a full preclinical development program and submitted an IND application to the FDA for KPI- 012 which was approved in December 2022, and in February 2023, we dosed our first patient in the CHASE Phase 2b clinical trial of KPI- 012 for PCED in the United States. We **have initiated several** ~~are also planning to add~~ clinical trial sites in **Argentina for the** ~~Latin America to our~~ CHASE Phase 2b **clinical** trial ~~, subject to regulatory approval~~ **and we are in the process of initiating additional clinical trial sites in Latin America** . If the FDA does not accept the data from any trial that we conduct outside the United States, it could delay or permanently halt our development of the applicable product candidates. ~~Public health epidemics, including the COVID- 19 pandemic, could impact the development of KPI- 012 or any other product candidate we may develop, and may adversely affect our business, results of operations and financial condition. Public health epidemics, including the COVID- 19 pandemic, may affect our ability to initiate and complete preclinical studies and clinical trials for KPI- 012 and any other product candidates we develop, including disruptions in procuring supplies that are essential for our research and development activities, manufacturing disruptions, disruptions in our ability to obtain necessary trial site approvals, as well as delays in or difficulties with enrollment and other delays at clinical trial sites. The public health emergency declarations related to COVID- 19 ended on May 11, 2023. The FDA ended certain COVID- 19 related policies and retained others. As a result of these and other measures, we may in the future face disruptions to our business. We do not know the extent to which public health epidemics, including the COVID- 19 pandemic, will impact our development of KPI- 012, including our ongoing CHASE Phase 2b clinical trial, or any other product candidates that we develop. Additionally, while we currently are not experiencing interruptions in our manufacturing of KPI- 012, any reinstatement of quarantines, travel restrictions and other measures related to a public health emergency may significantly impact the ability of employees of our third- party suppliers to get to their places of work to manufacture and deliver future supplies if and when needed. Public health epidemics may cause disruptions in financial markets, which could impact our ability to raise additional funds through public offerings and may also impact the volatility of our stock price and trading in our stock. Moreover, the impact of COVID- 19 on economies worldwide could result in adverse effects on our business and operations. While the public health emergency declared for the COVID- 19 pandemic has terminated, we cannot be certain what the overall impact of the COVID- 19 pandemic or any other public health emergencies or pandemics will be on our business in~~

~~the future and a continuation of the pandemic has the potential to adversely affect our business, financial condition, results of operations and prospects. 57Risks~~ -- **Risks** Related to the Commercialization of our Product CandidatesEven if KPI- 012 or any other product candidates that we may develop in the future receives marketing approval, such products may fail to achieve market acceptance by clinicians and patients, or adequate formulary coverage, pricing or reimbursement by third- party payors and others in the medical community, and the market opportunity for these products may be smaller than we estimate. If KPI- 012 or any other product candidate that we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by clinicians, patients, third- party payors and others in the medical community. We are developing KPI- 012 for PCED, which is a rare disease. Our understanding of both the number of people who have a PCED, as well as the subset of people with PCED diseases who have the potential to benefit from treatment with KPI- 012, are based on estimates. These estimates may prove to be incorrect. The number of patients with PCED may turn out to be lower than expected, may not be otherwise amenable to treatment with KPI- 012 or may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects. Biosimilar and generic versions of any products that compete with KPI- 012 or any other product candidates we may develop would likely be offered at a substantially lower price than we expect to offer for our product candidates, if approved. As a result, clinicians, patients and third- party payors may choose to rely on such products rather than our product candidates. Our assessment of the potential market opportunity for KPI- 012 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. While we believe these industry publications and third- party research, surveys and studies are reliable, we have not independently verified such data. The potential market opportunity for the treatment of PCED is difficult to precisely estimate. Our estimates of the potential market opportunities for KPI- 012 include several key assumptions based on our industry knowledge, industry publications, third- party research and other surveys, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for KPI- 012 for PCED may be smaller than we expect, and as a result our future product revenue may be limited and it may be more difficult for us to achieve or maintain profitability. If KPI- 012 or any other product candidate for which we may obtain marketing approval does not achieve adequate levels of acceptance by physicians and patients, formulary coverage, pricing or reimbursement, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of KPI- 012 or any other product candidate for which we may obtain marketing approval, will depend on a number of factors, including: ● the efficacy and potential advantages of our product candidates compared to alternative treatments, including the existing standard of care; **61** ● our ability to offer our products for sale at competitive prices, particularly in light of the lower cost of alternative treatments; ● the availability of third- party formulary coverage and adequate reimbursement; ● the clinical indications for which the product is licensed or approved; ● the convenience and ease of administration compared to alternative treatments; ● the willingness of the target patient population to try new therapies and of clinicians to prescribe these therapies; ● the strength of our marketing and distribution support; ● the timing of market introduction of competitive products; ~~58~~ ● the prevalence and severity of any side effects; and ● any restrictions on the use of our products together with other medications. Even if we are able to successfully commercialize KPI- 012 or any other product candidate that we may develop, if and when they are approved, 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 successfully commercialize KPI- 012 or any other product candidate that we may develop if and when they are approved 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 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 KPI- 012 or any other product candidate that we may commercialize and, even if they are available, the level of reimbursement may be limited or not satisfactory. Inadequate reimbursement may adversely affect the demand for, or the price of KPI- 012 or any other 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 KPI- 012 or any other product candidate if and when they are approved. There may be significant delays in obtaining coverage and reimbursement for newly approved products and coverage may be more limited than the indications for which the product is approved by the FDA or similar regulatory authorities outside the United States. Reimbursement agencies in Europe may be more conservative than the Centers for Medicare & Medical Services, or CMS, in the United States. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. Moreover, eligibility for coverage and reimbursement does not imply that a product 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 products, 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 product and the clinical setting in which it is used, may be based on reimbursement

levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products 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 ~~products~~ **62products** from countries where they may be sold at lower prices than in the United States. 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 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 sale price of a product 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. ~~59Adverse~~ **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. Even if a product candidate we develop is approved for sale in the United States or in other countries, there can be no assurance that such product candidate will be considered medically reasonable and necessary for a specific indication or cost- effective by third- party payors, or 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 such product candidate profitably. If we are unable to establish and maintain sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, if and when necessary, we may not be successful in commercializing KPI- 012 or any other product candidate that we may develop if and when they are approved. We established a sales, marketing and distribution infrastructure for the commercial launch of EYSUVIS and INVELTYS, and, as a company, we have limited experience in the sales, marketing and distribution of therapeutic products. Following the sale of our Commercial Business to Alcon in July 2022 and our determination to focus our research and development efforts on KPI- 012 and our MSC- S platform, we terminated our entire commercial sales force and certain employees in our commercial, scientific, manufacturing, finance and administrative functions. To achieve commercial success for any product for which we obtain marketing approval in the future, we will again need to establish sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties. There are risks involved with establishing, maintaining and expanding, if and when necessary, our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming, may divert our management and business development resources and could delay any future product launch. Establishing and maintaining a sales force would require us to continue to implement and improve our managerial, operational and financial systems, which we may not do effectively. Any inability to manage growth, when necessary, could delay the execution of our business plans or disrupt our operations. Further, we may overestimate or underestimate the size of the sales force required for a successful product launch. We have not yet established our own commercial organization or distribution capabilities specific to KPI- 012. While we believe that we will be able to commercialize KPI- 012, if approved, for the treatment of PCED with a small, targeted, internal sales force in the United States and potentially other major markets, our assumptions may prove inaccurate. In the future, we may need a larger sales force and at a higher cost than previously anticipated. If the commercial launch of any product candidate for which we establish a commercial infrastructure is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition any such sales, marketing and distribution personnel. ~~Factors~~ **63Factors** that may inhibit our efforts to commercialize on our own KPI- 012 or any other product candidate we develop, if and when approved, include: ● our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; ● our inability to obtain and maintain coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors; ● the inability of sales personnel to obtain access to clinicians or persuade adequate numbers of clinicians 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 establishing, maintaining and expanding, if and when necessary, an independent sales, marketing and distribution organization. While we cannot be certain when, if ever, we will seek and / or receive marketing approval to commercialize any of our product candidates outside the United States, we may seek marketing approval and explore commercialization of ~~60KPI~~ **KPI** - 012 in certain markets outside the United States utilizing a variety of collaboration, distribution, co- promotion and other marketing arrangements with one or more third parties. Our product revenues and our profitability, if any, under any such third- party collaboration, distribution or other marketing arrangements are likely to be lower than if we were to market, sell and distribute KPI- 012 ourselves. We may also consider seeking marketing approval outside the United States for other product candidates we may develop in the future. If we decide to seek regulatory approval for any of our product candidates outside the United States, we may need to seek additional patent approvals, seek licenses to patents held by third parties and / or face claims of infringing third- party patent rights. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute KPI- 012 or any other product candidate we may develop or we 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 effectively any product candidate for which we obtain marketing approval. If we do not establish and maintain our sales, marketing and distribution capabilities successfully,

when needed, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidate for which we obtain marketing approval. We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. Our competitors include major pharmaceutical companies with significantly greater financial resources. KPI- 012 and any other product candidate we may develop, if approved, will also compete with existing branded, generic and off- label products. The development and commercialization of new drug products is highly competitive. We face competition with respect to our product candidate, KPI- 012, and we will face competition with respect to any other product candidate that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. 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. If approved, we expect KPI- 012 to compete with Oxervate ®, which is the only approved prescription pharmaceutical product in the PCED space. Oxervate (cenegermin- bkbj) was approved in August 2018 for the treatment of neurotrophic keratitis, or NK, a degenerative disease characterized by decreased corneal sensitivity and poor corneal healing, which we believe to represent approximately one- third of all PCED cases. Oxervate is a topical eye drop that is administered six times per day at two- hour intervals for eight weeks. Each administration of Oxervate requires the use of a vial containing the drug product, a vial adapter, a single- use pipette and disinfectant wipes. To our knowledge, there are currently only two product candidates in active clinical development for the treatment of a broad PCED population. KIO- 201, a chemically modified form of the natural polymer hyaluronic acid administered as an eye drop, is currently being studied in a Phase 2 clinical trial in patients with PCED by Kiora Pharmaceuticals, Inc. Nexagon ®, an antisense ~~oligonucleotide~~ **64oligonucleotide** that inhibits connexin43 being developed by Amber Ophthalmics, is currently being studied in a Phase 2 / 3 clinical trial in patients with PCED ~~resulting from severe ocular chemical and / or thermal injuries. Amber Ophthalmics has also indicated that it plans to study Nexagon ® in a broad PCED population~~ . A number of companies are pursuing development of product candidates for the treatment of NK, including ReGenTree, LLC (Timbetasin ~~), Recordati S. p. A. (Udonitrectag~~) and Claris Biotherapeutics, Inc. (CSB- 001). We are also aware of potential competitors for KPI- 012 for Limbal Stem Cell Deficiency, or LSCD. Competitive products and product candidates in LSCD include two stem cell- based approaches. ABCB5 limbal stem cells, which are being studied in Phase 1 / 2 clinical trials and are being developed by RHEACELL GmbH & Co. KG, utilize allogeneic limbal stem cells derived from human corneal rims, which are expanded ex- vivo and manufactured as an advanced- therapy medicinal product. Holoclar utilizes autologous limbal stem cells derived from the healthy portion of the patient' s eye. Holoclar is approved in the European Union for treatment of LSCD caused by ocular burns and is developed by Chiesi. **Additionally, Claris Biotherapeutics, Inc. has initiated a Phase 1 study in LSCD of its recombinant hepatocyte growth factor product candidate, CSB- 001.** 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 products. Our competitors also may obtain FDA or other 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. Our competitors may develop products that are available on a generic basis, and our product candidates may not demonstrate sufficient additional clinical benefits to clinicians, patients or payors to justify a ~~61higher~~ -- **higher** price compared to generic products. In many cases, insurers or other third- party payors, particularly Medicare, seek to encourage the use of biosimilar and generic products. Many of the companies against which we are competing or which we may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, 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. Product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the use of our product candidates that we develop in human clinical trials, including KPI- 012. We face an even greater risk if we commercially sell any products that we may 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 products that we may 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 successfully commercialize any products that we may develop. ~~We~~ **65We** currently hold $ 10 million in product liability insurance coverage in the aggregate, with a per incident limit of $ 10 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage if we expand our ongoing and planned clinical trials for KPI- 012. We will need to further increase our insurance coverage when and if we begin commercialization of KPI- 012 or any other product candidate for which we obtain 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 PartiesWe have relied, 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. We have relied on third parties, such as clinical research organizations, clinical data management organizations, medical institutions and clinical investigators, in conducting our clinical trials and expect to

continue to rely on such parties to conduct clinical trials of any product candidate that we develop. We or these third parties may terminate their engagements with us at any time for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay our product development activities. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we 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 ~~62requires~~ -- **requires** us to comply with GCP standards 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. 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. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. We also have relied, and expect to continue to rely, on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of products, producing additional losses and depriving us of potential product revenue. We contract with third parties for the manufacture of KPI- 012 and plan to contract with third parties for preclinical, clinical and commercial supply of any other product candidates we develop. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We do not own or operate manufacturing facilities for the production of preclinical and clinical quantities of any product candidates. We do not own or operate, and currently have no plans to establish, any manufacturing facilities for KPI- 012. We rely, and expect to continue to rely, on third parties for the manufacture of both drug substance and finished product for KPI- 012 for preclinical and clinical testing, as well as for commercial manufacture of KPI- 012 if it receives marketing approval. We also rely, and expect to continue to rely, on third parties for packaging, labeling, sterilization, storage, distribution and other production logistics for KPI- 012. We have only limited supply agreements in place with respect to KPI- 012, and these arrangements do not extend to commercial supply. We obtain supplies of drug substance and finished product for KPI- 012 on a purchase order basis and do not have long term committed supply arrangements with respect to KPI- 012. We may be unable to maintain our current arrangements for KPI- 012 or enter into agreements for commercial supply of KPI- 012 on acceptable terms or at all. We also expect to rely on third- party manufacturers to manufacture preclinical, clinical and commercial supplies of any other product candidates we develop, as well as for packaging, serialization, storage, distribution and other production logistics. ~~We~~ **66We** are subject to risks related to our reliance on third- party manufacturers for the manufacture of the drug substance and product of KPI- 012, a biological product candidate. Manufacturing biologics is complex, especially in large quantities. Biologic products must be made consistently and in compliance with a clearly defined manufacturing process. KPI- 012 is a bone- marrow derived MSC- S therapeutic composed of biologically active components, including protease inhibitors and growth factors, and is produced from a proprietary cell bank. The manufacturing process for KPI- 012 is comprised of three stages: (1) cultivation of mesenchymal stem cells from a working cell bank and production of unprocessed conditioned media (cell- free secretome), (2) production of drug substance as a chemically defined solution and (3) formulation and filling of drug product. While the drug product for Combangio' s early research and Phase 1b clinical trial was cultivated using a planar culture model, we implemented a bioreactor cultivation model for our ongoing CHASE Phase 2b clinical trial of KPI- 012. We also plan to utilize a bioreactor cultivation model for our planned clinical trials and for commercial supply of KPI- 012. We are continuing the process of scaling up our manufacturing processes and capabilities with our third- party manufacturers to support longer term clinical development. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. In addition, KPI- 012 drug product is manufactured from a vial of a working cell bank, which in turn was produced from a vial of master cell bank. KPI- 012 master cell bank and working cell bank is stored in two separate locations. It is possible that we could lose the cell bank in both locations and have our manufacturing severely impacted by the need to replace the cell bank. Our third party manufacturers may encounter shortages in the raw materials necessary to produce our product candidates in the quantities needed for our clinical trials, or our product candidates, if approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials, including shortages caused by the purchase of such raw materials by our competitors or others and shortages related to epidemics or pandemics, such as the COVID- 19 pandemic. The failure of us or our third ~~63party~~ -- **party** manufacturers to obtain the raw materials necessary to manufacture sufficient quantities of KPI- 012 or any other product candidates we may develop, may have a material adverse effect on our business. The FDA maintains strict requirements governing the manufacturing process and third- party manufacturers are subject to inspection and approval by the FDA before a company can commence the manufacture and sale of any of its products or product candidates, and thereafter subject to FDA inspection from time to time. Failure by third- party manufacturers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to products or product candidates may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. Depending on the severity of any potential regulatory action, our clinical or commercial supply could be interrupted or limited, which could have a material adverse effect on our business. When a manufacturer seeks to modify or make even seemingly minor changes to the manufacturing process, the FDA may require the applicant to conduct a comparability study that evaluates the potential differences in the product resulting from the change in the manufacturing process. In connection with any application for approval to market product candidates in the United States, 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 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 nonrenewal 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 **current good manufacturing practice, or** cGMP **,** regulations or similar regulatory requirements outside the United States. 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 product candidates and harm our business and results of operations. ~~KPI~~ **67KPI** - 012 and any other product candidate 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 cGMP regulations. For example, we were previously required to change our third- party manufacturer when the manufacturer was purchased by a third- party and exited the contract manufacturing business. The process of changing manufacturers can cause substantial time delays, and if we are required to change our manufacturer again in the future, it may delay our ongoing and planned clinical trials or development timeline. Our current and anticipated future dependence upon others for the manufacture of KPI- 012 or any other product candidate 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. The manufacture of biologics is complex and our third- party manufacturers may encounter difficulties in production. If any of our third- party manufacturers encounter such difficulties, our ability to provide supply of product candidates for clinical trials or products for patients, if approved, could be delayed or prevented. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. ~~64In~~ **In** addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if we obtain regulatory approval for KPI- 012 or any product candidates we may develop in the future, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. ~~Our~~ **68Our** reliance on CIRM funding for KPI- 012 adds uncertainty to our research and development efforts, imposes certain compliance obligations on us and imposes requirements that may increase the costs of commercializing KPI- 012. Our development of KPI- 012 is currently being funded, in part, by an award from the California Institute for Regenerative Medicine, or CIRM. On August 2, 2023, our wholly- owned subsidiary, Combangio, entered into an award agreement with CIRM for a $ 15. 0 million grant, or the CIRM Award, to support the ongoing KPI- 012 program for the treatment of PCED as well as product and process characterization and analytical development for the program. The CIRM Award is subject to a co- funding requirement under which Combangio is obligated to spend a specified minimum amount on the development of KPI- 012 to obtain the full award amount and the remaining $ ~~9~~ **3** . ~~1~~ **3** million under the award is payable to Combangio only upon the achievement of specified milestones that are primarily related to Combangio' s progress in conducting the CHASE clinical trial. If we fail to satisfy the co- funding requirement under the CIRM Award or fail to achieve the milestones within the ~~timeframe~~ **timeframes** required by the CIRM Award, we may not receive full funding under the CIRM Award. CIRM may permanently cease disbursements under the CIRM Award if the milestones are not met within four months of their scheduled completion dates **or if the delay is not addressed to CIRM' s satisfaction, as determined by CIRM in its sole discretion** . We cannot be certain that we will achieve ~~such~~ **the remaining** milestones **under** ~~within the timeframe required by~~ the CIRM Award **within the required timeframes** , or at all, and as such we may never receive the remaining $ ~~9~~ **3** . ~~1~~ **3** million under the award. Additionally, if CIRM determines, in its sole discretion, that Combangio has not complied with the terms and conditions of the CIRM Award, CIRM may suspend or permanently cease disbursements. Moreover, disbursements under the CIRM Award are contingent upon the availability of funds in the state of California' s Stem Cell Research and Cures Fund, which is outside of our control. The CIRM Award also imposes financial conditions that may increase the costs of commercializing KPI- 012, if approved. Under the terms of the CIRM Award, Combangio is obligated to pay a royalty on net sales of any product, service or approved drug resulting in whole or in part from the CIRM Award in the amount of 0. 1 % per $ 1. 0 million of funds utilized by us until the earlier of 10 years from the date of first commercial sale of such product, service or approved drug and such time as nine times the amount of funds awarded by CIRM has been paid in royalties, or the Base Royalty. In addition, following the satisfaction of the Base Royalty,

Combangio is obligated to pay a 1. 0 % royalty on net sales of any CIRM- funded invention in excess of $ 500 million per year until the last to expire patent covering such invention expires. Additionally, there are significant compliance requirements associated with the CIRM Award, such as reporting, notification, recordkeeping and audit requirements, for which internal and external resources may be needed and which may increase our costs of doing business. Noncompliance with the requirements of the CIRM Award may cause a default under our Loan Agreement with Oxford Finance. It is an event of default under our Loan Agreement if we receive funding under the CIRM Award and are required to return such funds to CIRM in an amount in excess of $ 500, 000 due to our or Combangio' s failure to comply with the requirements of the CIRM Award, or if we are required to return funds to CIRM in excess of $ 1. 0 million due to non- utilization of such funds or because CIRM exercises its rights to recover such funds for any reason. Such an event of default could result in the acceleration of amounts due under our Loan Agreement. In such event, we may not be able to make accelerated payments, and the lender could seek to enforce security interests in the collateral securing such indebtedness. Acceleration of the repayment of the outstanding indebtedness would raise substantial doubt about our ability to continue as a going concern, shorten the period for which we will be able to fund our operations and capital expenditure requirements and would adversely affect our financial condition and ability to pursue our business strategy. ~~65In~~ **In** addition, as a result of the CIRM Award, we may not have the right to prohibit the State of California from using certain technologies developed by us. Under the CIRM Award, the California government can exercise march- in rights, which may include granting a third party nonexclusive, partially exclusive, or exclusive rights to CIRM- funded technology in any territory and field of use, if it determines that such action is necessary, if Combangio fails to make reasonable efforts to achieve practical application of a CIRM- funded technology, fails to comply with agreed to access and pricing requirements, or because action is necessary to address a public health emergency declared by the governor of California. ~~We~~ **69We** may enter into collaborations with 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 develop and commercialize KPI- 012 or any other product candidate we develop and for which we seek or obtain marketing approval in markets outside the United States. We also may enter into arrangements with third parties to perform these services in the United States if we do not establish our own sales, marketing and distribution capabilities in the United States for our product candidates or if we determine that such third- party arrangements are otherwise beneficial. We also may seek third- party collaborators for development and commercialization of our product candidates. For example, we may consider potential collaborative partnership opportunities prior to initiating IND- enabling studies on product candidates we may develop. 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. We are not currently party to any such arrangement. However, if we do enter into any such arrangements with any third parties in the future, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. 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. Collaborations that we enter into may pose a number of risks, including the following: ● collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations; ● collaborators may not perform their obligations as expected; ● collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities; ● collaborators may not pursue commercialization of our product candidates that receive marketing approval or may elect not to continue or renew commercialization programs based on changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities; ● collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; ● collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; ● product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own products or product candidates, which may cause collaborators to cease to devote resources to the commercialization of our product candidates; ~~66~~ ● a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products; ● disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to ~~product~~ **70product** candidates, or might result in litigation or arbitration, any of which would divert management attention and resources, be time- consuming and expensive; ● collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; ● collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability; and ● collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. Collaboration agreements may not lead to development or commercialization of product candidates or products in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we

may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these 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 herein 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 or 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. If we are not able to establish 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 or biotechnology companies for the development of our product candidates or the potential commercialization of our product candidates. 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 United States, 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 the potential commercialization of a product candidate or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization ~~67activities~~ **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. ~~Risks~~ **71Risks** Related to Our Intellectual Property We may be unable to obtain and maintain patent protection for our technology or product candidates, or the scope of the patent protection obtained may not be sufficiently broad or enforceable, such that our competitors could develop and commercialize technology, products and product candidates similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and product candidates, including KPI- 012. We have sought to protect our proprietary position by filing in the United States and in certain foreign jurisdictions patent applications related to our proprietary technologies and product candidates. The patent prosecution process is expensive and time- consuming, and we may not have filed, maintained, or prosecuted and may not be able to file, maintain and prosecute all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. 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 patent rights are highly uncertain. Our pending and future patent applications may fail to result in issued patents in the United States or in other foreign countries which protect our technology or product candidates, 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 United States, and the standards applied by the U. S. Patent and Trademark Office and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, unlike patent law in the United States, European patent law precludes the patentability of methods of treatment of the human body and imposes substantial restrictions on the scope of claims it will grant if broader than specifically disclosed embodiments. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain 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. Databases for patents and publications, and methods for searching them, are inherently limited so we may not know the full scope of all issued and pending patent applications. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies, products and product candidates. 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 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 United States and other countries may diminish the value of our

patents or narrow the scope of our patent protection. 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 for our proprietary technology and product candidates, 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, products or product candidates in a non- infringing manner. The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, ~~68in~~ **in** whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology, products or product candidates, or limit the duration of the patent protection of our technology and product candidates. 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~~ **72As** a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we are not able to obtain patent term extension in the United States under the Hatch- Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our product candidates, our business may be materially harmed. Depending upon the timing, duration, and specifics of FDA marketing approval of our product candidates, one of the U. S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch- Waxman Act. The Hatch- Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Also, the regulatory review period of an FDA- approved product may not serve as a basis for a patent term extension if the active ingredient of such product was subject to regulatory review and approval in an earlier product approved by the FDA. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be able to seek or be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration sooner, and our revenue could be reduced, possibly materially. It is possible that we will not obtain patent term extension under the Hatch- Waxman Act for a U. S. patent covering our product candidates even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the U. S. Patent and Trademark Office, a petition for patent term extension under the Hatch- Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch- Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the U. S. Patent and Trademark Office. We may become involved in lawsuits to protect or enforce our patents or other intellectual property rights, which could be expensive, time- consuming and unsuccessful. Competitors and other third parties may infringe, misappropriate or otherwise violate our owned and licensed patents, trade secrets, or other intellectual property rights. As a result, to counter infringement, misappropriation or unauthorized use, we may be required to file infringement or misappropriation claims or other intellectual property related proceedings, 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 infringe their patents or that our asserted patents are invalid. In addition, in a patent infringement or other intellectual property related 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, held unenforceable or interpreted narrowly, and could put any of our patent applications at risk of not yielding an issued patent. 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 or trade secrets could be compromised by disclosure during this type of litigation. ~~69We~~ **We** may be subject to a third- party preissuance submission of prior art to the U. S. Patent and Trademark Office, or become involved in other contested proceedings such as opposition, derivation, reexamination, inter partes review, post- grant review, or interference proceedings in the United States or elsewhere, 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~~ **73of**, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates 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. In the United States, the FDA does not prohibit clinicians from prescribing an approved product for uses that are not described in the product' s labeling. Although use of a product directed by off- label prescriptions may infringe our method- of- treatment patents, the practice is common across medical specialties, particularly in the United States, and such infringement is difficult to detect, prevent, or prosecute and may have negative impacts on our business, operating results and financial condition. Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the

outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market, and sell KPI- 012 and any other product candidate we may develop in the future and to use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is a considerable amount of intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, infringement litigation claims regarding our product candidates and technology, including claims from competitors or from non- practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Moreover, we may become party to future adversarial proceedings or litigation regarding our patent portfolio or the patents of third parties. Such proceedings could also include contested post- grant proceedings such as oppositions, inter partes review, reexamination, interference, or derivation proceedings before the U. S. Patent and Trademark Office or foreign patent offices. The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time- consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if our product candidates commence commercialization. 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 any of our product candidates or our development and commercialization thereof, do not and will not infringe or otherwise violate any third- party' s intellectual property. If we are found to infringe, misappropriate or otherwise violate a third- party' s intellectual property rights, we could be required to obtain a license from such third- party to continue developing, manufacturing, marketing and selling any products, if and when approved, product candidates 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 and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology, products or product candidates. 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 and could be forced to indemnify our customers or collaborators. A finding of infringement could also result in an injunction that prevents us from commercializing our product candidates or forces us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. ~~70Obtaining~~ **74Obtaining** and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance, renewal and annuity fees on any issued patent must be paid to the U. S. Patent and Trademark Office and foreign patent agencies in several stages or annually over the lifetime of our owned and licensed patents and patent applications. The U. S. Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we may rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business. KPI- 012 is protected by patent rights exclusively licensed from other companies or institutions. If these third parties terminate their agreements with us or fail to maintain or enforce the underlying patents, or we otherwise lose our rights to these patents, our competitive position and our market share in the markets for any of our products, if any when approved, will be harmed. A portion of our patent portfolio is in- licensed. As such, we are a party to license agreements and certain aspects of our business depend on patents and / or patent applications owned by other companies or institutions. In particular, we hold an exclusive license for a patent family relating to KPI- 012. We rely on a license from Stanford University for certain patent rights related to KPI- 012. The license agreement between Combangio and Stanford University, or Stanford University License Agreement, imposes specified diligence, milestone payment, royalty and other obligations on us and requires that we meet development timelines, or to exercise diligent or commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the license. Our rights with respect to in- licensed patents and patent applications may be lost if the applicable license agreement expires or is terminated or if we fail to satisfy the obligations under the Stanford University License Agreement. We are likely to enter into additional license agreements to in- license patents and patent applications as part of the development of our business in the future, under which we may not retain control of the preparation, filing, prosecution, maintenance, enforcement and defense of such patents. If we are unable to maintain these patent rights for any reason, our ability to develop and commercialize our product candidates could be materially harmed. Our licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third- party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability. Risks with respect to parties from whom we have obtained intellectual

property rights may also arise out of circumstances beyond our control. In spite of our best efforts, our licensors might conclude that we have materially breached our intellectual property agreements and might therefore terminate the intellectual property agreements, thereby removing our ability to market products covered by these intellectual property agreements. If our intellectual property agreements are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our intellectual property agreements are terminated, our former licensors and / or assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on our competitive business position and our financial condition, results of operations and our business prospects. ~~71Some~~ **75Some** intellectual property which we own or have licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as " march- in " rights, certain reporting requirements, and a preference for United States industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non- U. S. manufacturers. Some of the intellectual property rights we own or have licensed have been generated through the use of United States government funding and may therefore be subject to certain federal regulations. For example, certain aspects of KPI- 012 were developed using United States government funds. As a result, the United States government may have certain rights to intellectual property embodied in KPI- 012 pursuant to the Bayh- Dole Act of 1980, or Bayh- Dole. These United States government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has the right to require us to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third- party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as " march- in rights "). The United States government also has the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the United States government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the United States government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States manufacturers may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. Further, to the extent any of our current or future intellectual property is generated through the use of U. S. government funding, the provisions of Bayh- Dole may similarly apply. Accordingly, any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects. Moreover, in December 2023, the National Institute of Standards and Technology, or NIST, released for public comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights, or the Draft Framework. The Draft Framework sets forth the factors that an agency may consider when deciding whether to exercise march- in rights pursuant to Bayh- Dole, and includes a first- ever specification that price can be a factor in determining that a drug or other taxpayer- funded invention is not accessible to the public. NIST is currently seeking public comments on the proposed Draft Framework. The potential inclusion of price as a factor in a march- in determination and the exercise of " march- in " rights by the federal government could result in decreased demand for our future products, which could have a material adverse effect on our results of operations and financial condition. In addition, any failure to comply with applicable laws or regulations could harm our business and divert our management' s attention. If we fail to comply with our obligations ~~in~~ **under** our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business. Our Stanford University License Agreement, under which we license certain patent rights related to KPI- 012, imposes royalty and other financial obligations on us and other substantial performance obligations. We also may 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. 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 or product candidate that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of any product or product candidate. 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. ~~72In~~ **76In** addition, it is possible that Stanford may conclude that we have materially breached the Stanford University License Agreement and might therefore terminate the agreement, thereby removing our ability to market products covered by our license agreement with Stanford. If the Stanford University License Agreement is terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our Stanford University License Agreement is terminated, Stanford and / or its assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. If we breach the agreement (including by failing to meet our payment obligations) and do not adequately cure such breach, the rights in the technology licensed to us under the Stanford University License Agreement will revert to Stanford at no cost to Stanford. This could have a material adverse effect on our competitive

business position, our financial condition, our results of operations and our business prospects. In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize any affected product or product candidate, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. We may not be able to protect our intellectual property and proprietary rights throughout the world. Filing, prosecuting, and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Beginning June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court, or UPC. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. As the UPC is a new court system, there is minimal precedent for the court, increasing the uncertainty of any litigation. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of any potential changes. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially ~~73diminish~~ **77diminish** the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. 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. Many of our and our licensors' employees and contractors were previously employed at other biotechnology, medical device or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and contractors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these individuals 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. Furthermore, we are unable to control whether our licensors have obtained similar assignment agreements from their own employees and contractors. Our and their assignment agreements may not be self-executing or may be breached, and we or our licensors 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 or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third- party, and we could be required to obtain a license from such third- party to commercialize our technology or products, which may not be available on commercially reasonable terms or at all. 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 or other legal proceedings relating to intellectual property 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 and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on 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 our technology and our product candidates, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect 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. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling ~~74to~~ **78to** 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 MattersIf we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate significant 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 KPI- 012 or any product candidates we may develop in the future. KPI- 012 and any other future product candidate and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, potency, purity, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. Other than EYSUVIS and INVELTYS, which we sold to Alcon in July 2022, we have not received approval to market any product candidate from regulatory authorities in any jurisdiction. We may never generate the necessary data or results required to obtain regulatory approval of KPI- 012 or any other product candidate we may develop with the market potential sufficient to enable us to achieve profitability. We have only limited experience in submitting and supporting the applications necessary to gain marketing approvals and have relied on, and expect to continue to rely on, third- party consultants and vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish a biologic product candidate' s purity, safety 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 KPI- 012 or any other product candidate that we develop does not satisfy these standards or has undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. **Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or a comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.** The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. **In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan for each phase 3 clinical trial or any other " pivotal study " of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late- stage clinical 79trials of FDA- regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for diversity action plans. Unlike most guidance documents issued by the FDA, the diversity action plan**

guidance when finalized will have the force of law. Further, under the Pediatric Research Equity Act, or PREA, a **Biologics License Application, or** BLA or supplement to a BLA for certain biological products must contain data to assess the safety, potency and purity of the biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe, potent and pure, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety, potency and purity data need to be collected before the pediatric trials begin. The applicable legislation in the ~~EU~~ **European Union** also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the European Medicines Agency, or EMA, or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the United States or the European Union, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action. ~~75In~~ **In** addition, ~~disruptions at~~ **we could be adversely affected by several significant administrative law cases decided by the U. S. Supreme Court in 2024. In Loper Bright Enterprises v. Raimondo, for example, the court overruled Chevron U. S. A., Inc. v. Natural Resources Defense Council, Inc., which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U. S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as** the FDA ~~and~~ **acted within its statutory authority under** ~~other~~ -- **the Administrative Procedure Act,** ~~agencies may prolong the time necessary for~~ - **or the APA. Additionally** ~~new biologics to be reviewed and / or approved by necessary government agencies~~ , ~~which would adversely affect~~ **in Corner Post, Inc. v. Board of Governors of the Federal Reserve System, the** ~~our~~ **court held that actions** ~~business. The ability of the FDA~~ to ~~review and approve new biologics~~ **challenge a federal regulation under the APA** can be **initiated within six** ~~affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the FDA have fluctuated in recent~~ years **of** ~~. Over~~ the ~~last several years,~~ **date of injury to** the ~~U~~ **plaintiff, rather than the date the rule is finalized** . ~~S~~ **The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations** . **Another decision, Securities** ~~government has shut down several times~~ and ~~certain~~ **Exchange Commission v. Jarkesy, overturned** regulatory agencies **' ability to impose civil penalties in administrative proceedings. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies** , ~~such~~ **including the FDA and CMS, that we rely on. In addition to potential changes to regulations** as ~~the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, including as~~ a result of **legal challenges,** ~~Congress failing to timely raise the~~ **these decisions may result in increased** ~~U. S. debt ceiling, it could significantly impact the ability of the FDA to timely review and process our~~ regulatory ~~submissions~~ **uncertainty and delays and other impacts** . **any of** which could ~~have a material adverse~~ **adversely impact** ~~effect on~~ our business **and operations** . Further, our ability to develop and market new products may be impacted by ~~ongoing~~ litigation challenging the FDA' s approval of mifepristone. **In** ~~Specifically, in~~ April 2023, the U. S. District Court for the Northern District of Texas stayed the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various conditions adopted under a REMS. **The** ~~In reaching that decision, the district court made a number of findings that may negatively impact the development, approval and distribution of drug products in the United States. In April 2023, the district court decision was stayed, in part, by the U. S.~~ Court of Appeals for the Fifth Circuit ~~. Thereafter, the U. S. Supreme Court entered a stay of the district court' s decision, in its entirety, pending disposition of the appeal of the district court decision in the Court of Appeals for the Fifth Circuit and the disposition of any petition for a writ of certiorari to or the Supreme Court. In August 2023, the Court of Appeals~~ declined to order the removal of mifepristone from the market, **but** ~~finding that a challenge to the FDA' s initial approval in 2000 is barred by the statute of limitations. But the Appeals Court~~ did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone that FDA authorized in 2016 and 2021 were arbitrary and capricious. In ~~December~~ **June** ~~2023~~ **2024** , the Supreme Court ~~granted~~ **reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. On October 11, 2024, the Attorneys General of three states filed an amended complaint in the U. S. District Court for the Northern District of Texas challenging the FDA' s actions. In January 2025, the district court agreed to allow** these ~~petitions~~ **states to file an amended complaint and continue to pursue this challenge. Depending on the outcome of this litigation, if it continues, our ability to develop and market new drug products could be delayed, undermined** ~~for~~ - **or** ~~writ of certiorari for~~ **subject to protracted litigation. Further,** ~~the~~ **there** ~~appeals~~ **is substantial uncertainty as to how measures being implemented by the new Trump Administration across the government will impact the FDA, CMS and other federal agencies with jurisdiction over** ~~court~~ -- **our** ~~decision~~ **activities. For example, since taking office, President Trump has issued a number of executive orders, which could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities** . If **these or other orders or executive actions impose constraints on FDA' s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, the loss of FDA personnel could lead to further disruptions and delays in FDA review and oversight of our product candidates. Similarly, efforts by the new administration to substantially reduce or delay research funding by the National Institutes of Health of medical research could have substantial direct or indirect impacts on our research activities. 80If** we experience delays in obtaining approval or if we fail to obtain approval of any product candidate that we develop, the commercial prospects for such product candidate may be harmed and our ability

to generate revenues will be materially impaired. Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. We may be subject to additional risks in commercializing any of our product candidates that receive marketing approval in foreign jurisdictions. In order to market and sell KPI- 012 or any other product candidate we may develop in the European Union and many other jurisdictions outside of the United States, we or our potential 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. Clinical trials of any product candidate in the United States may not be sufficient to support an application for marketing approval outside the United States. The time required to obtain approval outside of the United States may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be sold in that country. We or our potential collaborators may not obtain approvals from regulatory authorities outside the United States 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 United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market, which could significantly and materially harm our business. **Additionally, we could face heightened risks with respect to obtaining marketing authorization in the United Kingdom as a result of the withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The UK is no longer part of the European Single Market and EU Customs Union. As of January 1, 2025, the Medicines and Healthcare Products Regulatory Agency, or MHRA, is responsible for approving all medicinal products destined for the United Kingdom market (i. e., Great Britain and Northern Ireland). At the same time, a new international recognition procedure, or IRP, will apply, which intends to facilitate approval of pharmaceutical products in the United Kingdom. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA' s specified Reference Regulators, or RRs, The RRs notably include EMA and regulators in the European Union / European Economic Area member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the United States). However, the concrete functioning of the IRP is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals may force us or our collaborators to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.** In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the European Union pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission' s proposal for revision of several legislative instruments related to medicinal products (including potentially reducing the duration of regulatory data protection and **exclusivity periods for orphan drugs, and** revising the eligibility for expedited pathways) was published ~~on~~ **in** April ~~26,~~ 2023 **and the European Parliament has requested several amendments** . The proposed revisions remain to be agreed and adopted by the European ~~76Parliament --~~ **Parliament** and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term. ~~Even~~ **81Even** if our product candidates receive regulatory approval, they will be subject to significant post- marketing regulatory requirements and oversight. Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and ongoing surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post- approval study or risk management requirements and regulatory inspection. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labelling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as ongoing compliance with cGMPs and GCPs for any clinical trials that we conduct post- approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA and other regulatory authorities for compliance with cGMP regulations and standards. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug or biologic undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including: ● delays in or the rejection of product approvals; ● restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials; ● restrictions on the products, manufacturers or manufacturing process; ● warning or untitled letters; ● civil and criminal penalties; ● injunctions; ● suspension or withdrawal of

regulatory approvals; ● product seizures, detentions or import bans; ● voluntary or mandatory product recalls and publicity requirements; ● total or partial suspension of production; ● imposition of restrictions on operations, including costly new manufacturing requirements; ● revisions to the labelling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings; ● imposition of a REMS, which may include distribution or use restrictions; ~~and~~ **and82** ● requirements to conduct additional post- market clinical trials to assess the safety of the product. ~~77The~~ -- **The** FDA, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off- label uses, and if we are found to have improperly promoted such off- label uses, we may become subject to significant liability. If any of our product candidates are approved and we are found to have improperly promoted off- label uses of those products, we may become subject to significant liability, which would materially adversely affect our business and financial condition. The FDA, EMA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted in the United States for uses that are not approved by the FDA as reflected in the product' s approved labelling, or in other jurisdictions for uses that differ from the labelling or uses approved by the applicable regulatory authorities. While physicians may prescribe products for off- label uses, the FDA, EMA and other regulatory authorities actively enforce laws and regulations that prohibit the promotion of off- label uses by companies, including promotional communications made by companies' sales force with respect to off- label uses that are not consistent with the approved labelling. The U. S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. ~~Notwithstanding~~ **We will also need to carefully navigate** the **FDA' s various** ~~regulatory~~ **regulations , guidance and policies, along with recently enacted legislation, to ensure compliance with** restrictions **governing** ~~on off- label~~ promotion **of** ~~, the FDA and other regulatory authorities allow companies to engage in truthful, non- misleading, and non- promotional scientific communications concerning their~~ products ~~in certain circumstances~~ . **In September** ~~For example, in October 2023~~ **2021** , the FDA published ~~draft guidance outlining~~ **final regulations which describe** the **types** ~~agency' s non- binding policies governing the distribution~~ of **evidence that** ~~scientific information on unapproved uses to healthcare providers. This draft guidance calls for such communications to be truthful, non- misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret~~ the **FDA will consider in determining** ~~strengths and weaknesses and validity and utility of~~ the **intended** ~~information about the unapproved~~ use **of a drug or biologic** . **Moreover** ~~In addition~~ , **with passage of** ~~under some relatively recent guidance from the FDA and~~ the Pre- Approval Information Exchange Act **in December** ~~signed into law as part of the Consolidated Appropriations Act of 2023~~ **2022** , ~~companies~~ **sponsors of products that have not been approved** may ~~also promote~~ **proactively communicate to payors certain** information ~~that~~ **about products in development to help expedite patient access upon product approval. In addition, in January 2025, the FDA published final guidance outlining** ~~is~~ **its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non- misleading and scientifically sound and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use of the approved product. If a company engages in such communications** consistent with the ~~prescribing information and proactively speak to formulary committee members~~ **guidance' s recommendations, the FDA indicated that it will not treat such communications as evidence** of **unlawful promotion of a new intended** ~~payors regarding data for an unapproved drug or unapproved uses~~ - **use** ~~of an~~ **for the** approved **product** ~~drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices~~ . We will need to carefully navigate the FDA' s various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. We may not be able to obtain orphan drug exclusivity for one or more of our product candidates, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products. Additionally, if another company with a competing product candidate were to obtain orphan drug exclusivity for its competing product candidate before we do, we may be barred from marketing our product candidate for the same indication as the competing product candidate during the exclusivity period. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. KPI- 012 has received orphan drug designation from the FDA for the treatment of PCED. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and **currently** ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified. If a competing product candidate with an orphan designation for PCED were to obtain ~~regulatory~~ **83regulatory** approval before we are able to obtain approval of KPI- 012 for PCED, we could be barred from marketing KPI- 012 for PCED in the United States during the seven- year orphan exclusivity period, which would have a severe adverse effect on our business. ~~78In~~ **In** order for the FDA to grant orphan drug exclusivity to one of our products, the FDA must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200, 000 individuals annually in the United States. The FDA may conclude that the condition or disease for which orphan drug exclusivity is sought does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may

not effectively protect the product from competition because different products can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition. The FDA Reauthorization Act of 2017, or FDARA, requires that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. FDARA reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term " same disease or condition " means the designated " rare disease or condition " and could not be interpreted by the FDA to mean the " indication or use. " Thus, the Court of Appeals concluded that orphan drug exclusivity applies to the entire designated disease or condition rather than the " indication or use. " Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, **the** FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan- drug exclusivity to the uses or indications for which the orphan drug was approved. **However, on February 14, 2025, a federal district court in Washington, D. C. fully embraced the reasoning of the court decision in another decision challenging the scope of orphan drug exclusivity. The implications of this decision, and its impact on the FDA' s implementation of the Orphan Drug Act, are unclear at this point.** We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. ~~We~~ **In addition, to obtain orphan drug designation in the European Union, we would need to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the medicinal product will be of significant benefit to those affected by that condition. There is no assurance that we would be able to meet that standard for any of our product candidates. Further, if we do obtain orphan drug designation for a product candidate in the European Union, we will not be able to maintain that designation if we are not able to show, to the satisfaction of the European Union regulatory authorities, that the product candidate is of significant benefit to patients over available commercial products for the indication in the European Union and any additional products that are ahead of our product candidate in clinical development for the indication. 84We** may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review designations in the United States, and PRIME Designation in the European Union, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process. We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track review products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product' s application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track review product may be effective. In April 2023, the FDA designated KPI- 012 for the treatment of PCED for Fast Track review. We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate **is intended to treat a serious condition and, if approved,** offers ~~major advances in treatment or provides~~ a ~~treatment where no adequate therapy exists~~ **significant improvement in safety or effectiveness** , the FDA may designate the product candidate for priority review. A priority review designation means that the goal is for the FDA to review an application for marketing approval in six months, rather than the standard review period of 10 months. ~~79These~~ -- **These** designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, such as the Fast Track designation for KPI- 012 for the treatment of PCED, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In the European Union, we may seek PRIME designation for some of our product candidates in the future. The PRIME program focuses on product candidates that target conditions for which there exists no satisfactory method of treatment in the European Union, or even if such a method exists, the product candidate may offer a major therapeutic advantage over existing treatments. To be accepted for PRIME designation, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the

claims. The benefits of a PRIME designation include the appointment of a rapporteur of the Committee for Medicinal Products for Human Use to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME designation enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA' s grant of a marketing authorization. ~~If~~ **85If** approved, our products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA- licensed reference biologic product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12- year period of regulatory exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity, and potency of the other company' s product. In December 2022, Congress clarified through the Food and Drug Omnibus Reform Act, that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the same first day on which such a product is approved as interchangeable with the reference product and the exclusivity period may be shared amongst multiple first interchangeable products. More recently, in October 2023, the FDA issued its first interchangeable exclusivity determination under the BPCIA. To date, we have not had a product candidate approved as a biologic product. We believe that any of our product candidates that may be approved as a biologic product under a BLA should qualify for the 12- year period of exclusivity. Nonetheless, the approval of biosimilar products referencing any of our product candidates would have a material adverse impact on our business due to increased competition and pricing pressures. Moreover, there is a risk that any exclusivity we do receive could be shortened due to congressional action or otherwise, or that the FDA will not consider our products to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. The extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain regulatory approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. ~~80The~~ -- **The** ultimate impact, implementation, and meaning of the BPCIA are subject to uncertainty, and any new regulations, guidance, policies or processes adopted by the FDA to implement the law could have a material adverse effect on the future commercial prospects for our biological product candidates. 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, clinicians and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription and use of any product candidates 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. 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. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it in order to have committed a violation; **86** ● 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. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; ● 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; ● the federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with

specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or transfers of value made to physicians, other healthcare providers and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; 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 clinicians 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. ~~81If~~ **If** our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, individual imprisonment, integrity obligations, and the curtailment or restructuring of our operations. Any penalties, damages, fines, individual imprisonment, integrity obligations, exclusion from funded healthcare programs, or curtailment or restructuring of our operations could adversely affect our financial results. Our corporate compliance program is designed to ensure that we will develop, market and sell our products and product candidates in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. 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 clinicians or other healthcare providers or entities with whom we do or expect to do business is found to be ~~not~~ **87not** in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs. Existing and future legislation may affect our ability to commercialize our products, if and when approved, and increase the difficulty and cost for us to obtain reimbursement for our products, if and when approved. In the United States 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 for which we obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and have 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 FDA approved product. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2021, the Budget Control Act of 2011, among other things, led to aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year which went into effect in 2013 and will remain in effect through the first half of 2032. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any product candidate is prescribed or used. Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4 %. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4 % Statutory PAYGO sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4 % cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriations Act' s health care offset title includes Section 4163, which extends the 2 % Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031. We expect that additional healthcare reforms may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any product which receives regulatory approval and / or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or ~~82administered~~ -- **administered** . Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Since enactment of the ACA, there have been and continue to be numerous legal challenges and Congressional actions to repeal and replace provisions of the law and litigation and legislation over the ACA is likely to continue with unpredictable and uncertain results. For example, with enactment of the Tax Cuts and Jobs Act of 2017, or the 2017 Tax Act, ~~which was signed by President Trump on December 22, 2017,~~ Congress repealed the " individual mandate. " The repeal of this provision, which required most Americans to carry a minimal level of health insurance, became effective in 2019. ~~The~~ **In June 2021, the U. S. Supreme Court**

dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Shortly after taking office in January 2025, President Trump **revoked numerous** ~~Administration also took~~ executive **orders issued** ~~actions to undermine or delay implementation of the ACA, but those were rescinded~~ by ~~the Biden Administration.~~ President Biden ~~issued an~~ **, including at least two** executive ~~order~~ **orders** which ~~directs federal agencies~~ **where were designed** to ~~reconsider rules~~ **further implement the ACA. We anticipate similar efforts to undermine the ACA, and the accompanying uncertainty, for the foreseeable future. Further, the recent election of President Trump, coupled with a consolidation of party control of both chambers of the U. S. Congress, has led to new legislative and regulatory initiatives in the United States and the roll- back of many initiatives of the previous presidential administration, which may impact our business in unpredictable ways. Market uncertainty and volatility have been magnified and may intensify due to the statements and actions of the new U. S. presidential administration and resulting uncertainties regarding actual and potential shifts in U. S. and foreign, trade, economic** and other policies ~~that limit Americans' access to health care~~ , **including** ~~and consider actions that will protect and strengthen that access. Under this executive order, federal agencies are directed to re- examine: policies that undermine protections for people~~ with ~~pre-existing conditions, including complications related to COVID- 19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents. We expect~~ **respect** ~~that additional healthcare reforms may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any product which receives regulatory approval and / or the level of reimbursement physicians receive for administering any approved product we might bring~~ to ~~market~~ **treaties and tariffs** . ~~Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Current~~ **88Current** and future legislation designed to reduce prescription drug costs may affect the prices we and any collaborators may obtain for our product candidates. The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several ~~recent~~ U. S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid ~~. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician- administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence- based care~~ . In October 2020, Health Insurance Portability and Accountability Act of 1996, or HHS, and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by **the Pharmaceutical Research and Manufacturers of America, or** PhRMA **,** but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. ~~At least nine~~ **A few states have passed legislation establishing workgroups to examine the impact of a state importation program. Several** states have passed laws allowing for the importation of drugs from Canada. Certain ~~of these~~ states have submitted Section 804 Importation Program proposals and are awaiting FDA approval. On January 5, 2024, the FDA approved Florida' s plan for Canadian drug importation. **Florida now has authority to import certain drugs from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre- import request for each drug selected for importation, which must be approved by the FDA. Florida will also need to relabel the drugs and perform quality testing of the products to meet FDA standards.** Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point- of- sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe ~~83harbors~~ -- **harbors** were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. The Inflation Reduction Act of 2022, or IRA, further delayed implementation of this rule to January 1, 2032. The IRA has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare ~~(~~beginning in 2026 ~~)~~, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation ~~(first due in 2023);~~ and replaces the Part D coverage gap discount program with a new discounting program ~~(~~beginning in 2025 ~~)~~. The IRA permits the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single- source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high- cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028 and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13

years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years. **On August 15, 2024, HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations. CMS issued a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program. The second cycle of negotiations with participating drug companies will occur during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027.** ~~Further~~ **89Further** , the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated " maximum fair price " under the law or for taking price increases that exceed inflation. The ~~legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new~~ law also caps Medicare out- of- pocket drug costs at an estimated $ ~~4~~ **2** , 000 a year **beginning** in **2025. In addition to the drug price negotiation program, the IRA established inflation rebate programs under Medicare Part B and Part D. These programs require manufacturers to pay rebates to Medicare if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. On December 9,** 2024 ~~and~~ , ~~thereafter beginning in~~ **with the issuance of its** 2025 **Physician Fee Schedule final regulation** , ~~at 2, 000 a year~~ **CMS finalized its rules governing the IRA inflation rebate programs** . Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition. For example, based on current guidance from CMS concerning the application of the IRA' s drug pricing provisions to orphan drugs, we may be eligible for reduced reimbursement if and when, if ever, KPI- 012 is approved as an orphan drug for PCED and a different rare disease or condition. On June 6, 2023, Merck & Co. filed a lawsuit against HHS and CMS asserting that, among other things, the IRA' s Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, other parties, including the U. S. Chamber of Commerce and certain pharmaceutical companies have also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. **There have been various decisions by the courts considering these cases since they were filed.** We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results. Further, in December 2023, NIST released for public comment ~~a Draft Interagency Guidance Framework for Considering~~ the ~~Exercise of March- In Rights, or the "~~ Draft Framework. The Draft Framework sets forth the factors that an agency may consider when deciding whether to exercise march- in rights pursuant to Bayh- Dole, and includes a first- ever specification that price can be a factor in determining that a drug or other taxpayer- funded invention is not accessible to the public. NIST is currently seeking public comments on the proposed Draft Framework. The potential inclusion of price as a factor in a march- in determination and the exercise of " march- in " rights by the federal government could result in decreased demand for our future products, which could have a material adverse effect on our results of operations and financial condition. In addition, any failure to comply with applicable laws or regulations could harm our business and divert our management' s attention. ~~84At~~ **At** the state level, individual states are increasingly aggressive in 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, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures **. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA' s standards for accelerated approval. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns personnel losses, or regulatory reform could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business. 90The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Further, while the FDA' s review of BLAs and other applications is funded through the user fee program established under PDUFA, the Trump Administration has indicated that it will be**

reviewing that program and its implementation. Disruptions at the FDA, EMA and other agencies may also slow the time necessary for new drugs or biologics to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U. S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC had to furlough critical employees and stop critical activities. In addition, disruptions may result from events similar to the COVID- 19 pandemic. During the COVID- 19 pandemic, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities. Further, there is substantial uncertainty as to how measures being implemented by the new Trump Administration across the government will impact the FDA, CMS and other federal agencies with jurisdiction over our activities. For example, since taking office, President Trump has issued a number of executive orders, which could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities. If these or other orders or executive actions impose constraints on FDA' s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. For example, the potential loss of FDA personnel could lead to further disruptions and delays in FDA review of our product candidates. Similarly, efforts by the new administration to substantially reduce or delay research funding by the National Institutes of Health of medical research could have substantial direct or indirect impacts on our research activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets . If we or any third- party manufacturers we engage or may engage in the future 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 any third- party manufacturers we engage or may engage in the future 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 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 general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, 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~~ **91production** 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 any future 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. We are subject to anti- corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing, manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition. Our operations are subject to anti- corruption laws, including the U. S. Foreign Corrupt Practices Act, or FCPA, the U. K. Bribery Act 2010, or Bribery Act, and other anti- corruption laws that apply in countries where we do business and may do business in the future. The FCPA, Bribery Act and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, 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. We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to ~~85liability~~ -- **liability** under the FCPA, Bribery Act or local anti- corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange

regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, 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. If we expand our presence outside of the United States, it will 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 United States, which could limit our growth potential and increase our development costs. There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti- corruption laws, including the FCPA, the Bribery Act or other legal requirements, including Trade Control laws. If we are not in compliance with the FCPA, Bribery Act and other anti- corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. Any investigation of any potential violations of the FCPA, the Bribery Act, other anti- corruption laws or Trade Control laws by U. S., U. K. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition. **On February 10, 2025, President Trump issued an executive order directing the Attorney General to review the guidelines and policies governing FCPA investigations and enforcement actions. Per the executive order, this review will result in new DOJ FCPA guidelines intended to enhance American economic competitiveness and to safeguard national 92security interests. During the 180- day review period, any new FCPA investigations and enforcement actions are to be suspended absent authorization from the Attorney General, and all existing FCPA investigations and enforcement actions will be reviewed. Additionally, after the Attorney General issues revised guidelines, the executive order directs the Attorney General to assess whether " remedial measures " related to past FCPA actions are warranted. We will need to carefully monitor the implementation of this order.** We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations. We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally- identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the U. S., EU and U. K. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects. There are numerous U. S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future **. In recent months, the Office of Civil Rights at HHS, or OCR, has been especially active in enforcing the HIPAA rules. Additionally, OCR is looking to amend the HIPAA Security Rule, which (if and when finalized) could create additional compliance obligations and risk for our business** . If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be ~~86interpreted --~~ **interpreted** , enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. In addition to potential enforcement by HHS, we are also potentially subject to privacy enforcement from the Federal Trade Commission, or the FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be " unfair " under Section 5 of the Federal Trade Commission Act, as well as the types of activities it views to trigger the Health Breach Notification Rule, which the FTC also has the authority to enforce. The FTC is also in the process of developing rules related to commercial surveillance and data security that may impact our business. We will need to account for the FTC' s evolving rules and guidance for proper privacy and data security practices in order to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and data security practices, which may impact our business. We may also be required to pay fines as part of a settlement, depending on the nature of the alleged violations. If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements **. Finally, both the FTC and HHS' s enforcement priorities (as well as those of other federal regulators) may be impacted by the change in administration and new leadership. These shifts in enforcement priorities may also impact our business. 93There are**

also increased restrictions at the federal level relating to transferring sensitive data outside of the United States to certain foreign countries. For example, in 2024, Congress passed H. B. 815, which included the Protecting Americans' Data from Foreign Adversaries Act of 2024. This law creates certain restrictions for entities that disclose sensitive data (including potential health data) to countries such as China. Failure to comply with these rules can lead to a potential FTC enforcement action. Additionally, the DOJ recently finalized a rule implementing Executive Order 14117, which creates similar restrictions related to the transfer of sensitive U. S. data to countries such as China. These data transfer restrictions (and others that may pass in the future) may create operational challenges and legal risks for our business . States are also active in creating specific rules relating to the processing of personal information. In 2018, California passed into law the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA' s requirements are similar to those found in the General Data Protection Regulation, or GDPR, described below, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt- out of " sales " of their personal information. The CCPA contains significant penalties for companies that violate its requirements. The California Privacy Rights Act, or the CPRA, went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR- like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA, and other California privacy laws, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities. In addition to California, a number of other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime ~~before~~ **over** the ~~end of 2026~~ **next few years** . Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of " sensitive " data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the ~~2024~~ **2025** legislative sessions. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. **For example, Washington state passed a health privacy law in 2023 which regulates the collection and sharing of health information that is not otherwise regulated by HIPAA rules, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation in 2025.** These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products **, if approved. Plaintiffs' lawyers in the United States are also increasingly using privacy- related statutes at both the state and federal level to bring lawsuits against companies for their data- related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act. The rise in these types of lawsuits creates potential risk for our business. Additionally, laws in all 50 states require businesses to provide notice to customers whose personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify affected individuals or other counterparties of a security breach, incident, or compromise. Although we may have contractual protections with our vendors, any actual or perceived security breach, incident, or compromise could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach, incident, or compromise. Any contractual protections we may have from our vendors may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections. In addition to government regulation, privacy advocates and industry groups 94have and may in the future propose self- regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply** . Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe, Latin America and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross- border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and / or fines of up to 20 million Euros or up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. ~~87The~~ -- **The** GDPR places restrictions on the cross- border transfer of personal data from the ~~EU~~ **European Union** to countries that have not been found to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the ~~EU~~ **European Union** to other countries. In July 2020,

the Court of Justice of the European Union, or CJEU, invalidated the EU- U. S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision has resulted in increased scrutiny on data transfers generally and may increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners. Additionally, in October 2022, President Biden signed an executive order to implement the EU- U. S. Data Privacy Framework, which serves as a replacement to the EU- U. S. Privacy Shield. The European Commission adopted the adequacy decision in July 2023. The adequacy decision permits U. S. companies who self- certify to the EU- U. S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU- U. S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU- U. S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business. Beyond GDPR and similar laws in the United States, there are privacy and data security laws in a growing number of countries around the world, including countries in Latin America where we ~~are planning to open~~ **have initiated several clinical** trial sites in the CHASE Phase 2b clinical trial. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws may impact our ability to conduct our business activities. While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non- compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government- imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects. ~~We~~ **95We** might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards. As of December 31, ~~2023~~ **2024**, we had federal net operating loss, or NOL, carryforwards of $ ~~369~~ **405**. ~~3~~ **5** million, which may be available to offset future federal tax liabilities and expire at various dates beginning in 2030. As of December 31, ~~2023~~ **2024**, we also had state NOL carryforwards of $ ~~413~~ **469**. ~~7~~ **1** million, which may be available to offset future state income tax liabilities and expire at various dates beginning in ~~2024~~ **2025**. As of December 31, ~~2023~~ **2024**, we had $ ~~1, 154~~ **2. 5 million** federal and state research and development credit carryforwards. Our NOL carryforwards could expire unused and be unavailable to offset our future income tax liabilities. In general, under Sections 382 and 383 of the Code, the amount of benefits from our NOL and research and development tax credit carryforwards, respectively, may be impaired or limited if we incur an " ownership change, " generally defined as a greater than 50 % change (by value) in our equity ownership by certain stockholders, over a three- year period. We previously completed an analysis and determined that an ownership change has materially limited our net operating loss carryforwards and research and development tax credits available to offset future tax liabilities. During December 2022, an additional ownership change occurred as a result of our entry into the securities purchase agreement for the private placement transaction. As a result of this ownership change, the utilization of our net operating loss carryforwards is subject to an annual limitation of $ 0. 2 million. We may be further limited by any changes that may have occurred or may occur subsequent to December 31, 2022. Any such limitations may result in greater tax liabilities than we would incur in the absence of such limitations and increased liabilities could adversely affect our business, ~~88results~~ -- **results** of operations, financial position and cash flows. If our ability to use our historical NOL and research and development tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs and research and development tax credit carryforwards could expire or otherwise become unavailable to offset future income tax liabilities. As described below in " Changes in tax laws or in their implementation or interpretation could adversely affect our business and financial condition, " the 2017 Tax Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, includes changes to U. S. federal tax rates and the rules governing NOL carryforwards that have significantly impacted our ability to utilize our NOLs to offset taxable income in the future. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we will likely be unable to use a material portion of our NOLs and other tax attributes. ~~Risks~~ **96Risks** Related to Employee Matters Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. We are highly dependent on the research and development, clinical, business development and commercialization expertise of ~~Mark Iwicki~~ **Todd Bazemore**, our **interim** Chief Executive Officer, ~~Todd Bazemore, our~~ President and Chief Operating Officer, Mary Reumuth, our Chief Financial Officer, Kim Brazzell, Ph. D., our Head of Research and Development and Chief Medical Officer ~~,~~ **and** Darius Kharabi, our Chief Business Officer ~~, and Eric L. Trachtenberg, our Chief Legal Officer, Chief Compliance Officer and Corporate Secretary~~, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain " key person " insurance for any of our executives or other employees. In addition, we are highly dependent on the employees who joined us in connection with the Combangio Acquisition and their expertise developing

biologics. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and other 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. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our decision to sell our Commercial Business to Alcon, our determination to solely focus our research and development efforts on our MSC- S platform, including KPI- 012, ~~and our workforce reduction completed during the second half of 2022~~ could harm our ability to attract and retain qualified personnel who are critical to our business. In addition, we rely on consultants and advisors, including scientific, clinical and regulatory 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 successfully develop and commercialize KPI- 012 and any other product candidate we may develop in the future will be harmed. Our internal computer systems, or those of our vendors, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs. Despite the implementation of security measures, our information technology systems and those of our current and any future vendors, contractors or consultants, including any collaborator, are vulnerable to damage from cyber- attacks, computer viruses, worms and other destructive or disruptive software, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Cyber incidents or attacks could include the deployment of harmful malware, ransomware, denial- of- service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. ~~89Cyber~~ -- **Cyber** incidents also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. System failures, accidents, cyberattacks or security breaches could cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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, personal or proprietary information, we could incur liability, including civil fines and penalties under the GDPR, HIPAA and other relevant state and federal privacy laws in the United States and abroad, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. In addition, we may not have adequate insurance coverage to provide compensation for any losses associated with such events. While we have not experienced any material losses relating to cyber- attacks, we have been the subject of a successful phishing attempt. We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our ~~company~~ **97company** , including personal information of our employees. In addition, outside parties may attempt to penetrate our systems or those of our vendors, contractors or consultants or fraudulently induce our employees or employees of our vendors, contractors or consultants to disclose sensitive information in order to gain access to our data. Like other companies, we may experience threats to our data and systems, including malicious codes and viruses, and other cyber- attacks. The number and complexity of these threats continue to increase over time. If a material breach of our security or that of our vendors, contractors or consultants occurs, the market perception of the effectiveness of our security measures could be harmed, we could lose business and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. A partially or fully remote workplace could negatively impact our business. **Although** ~~We terminated our lease for office and laboratory space at our former corporate headquarters in Watertown, Massachusetts, effective January 11, 2022. While~~ we have ~~retained~~ a nominal amount of office space on a short- term basis to conduct in- person meetings from time- to- time in Arlington, Massachusetts and lease office and laboratory space in Menlo Park, California, the vast majority of our employees no longer have individual offices. As a result, our management team and the vast majority of our employees will work remotely and without dedicated office space, until such time as we determine to obtain a new operating lease. **Our** ~~By migrating to a remote workforce, our~~ employees are accessing our servers remotely through home or other networks to perform their job responsibilities, which may be less secure. The risk of cyber incidents or other privacy or data security incidents may be heightened as a result of our remote work environment. Remote working arrangements could also impact employee productivity and morale, impede employee training, strain our technology resources and introduce operational risks, all of which could negatively impact our business. ~~Furthermore, our transition to a largely remote workplace will increase our reliance on third parties to conduct a significant portion of our research and development activities.~~ We have limited ability to control the amount or timing of resources that any such third party will devote to our research and development activities, and such third parties may terminate their engagements with us at any time. We also expect to have to negotiate budgets and contracts with such third parties, and we may not be able to

do so on favorable terms, which may result in delays to our development timelines and increased costs. ~~90Risks --~~ **Risks** Related to Our Common Stock If we fail to comply with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. If our common stock is delisted from Nasdaq, we will be in default under our Loan Agreement. Our common stock is currently listed on The Nasdaq Capital Market. We must satisfy Nasdaq' s continued listing requirements, including, among other things, a minimum closing bid price of $ 1. 00 per share and either a minimum stockholders' equity of $ 2, 500, 000, or a minimum market value of our common stock of at least $ 35, 000, 000, or risk delisting, which would have a material adverse effect on our business. There are many factors that may adversely affect our ability comply with the requirements for continued listing on The Nasdaq Capital Market, including those described throughout this " Risk Factors " section. Many of these factors are outside of our control. As a result, we cannot assure you that we will continue to comply with the requirements for continued listing on The Nasdaq Capital Market, including the minimum stockholders' equity requirement. A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors and employees and fewer business development opportunities. In addition, any potential delisting of our common stock from Nasdaq would also make it more difficult for our stockholders to sell their shares in the public market. We have a history of receiving deficiency letters from Nasdaq. During 2022, we received multiple deficiency letters from Nasdaq notifying us of our noncompliance with various listing standards for continued inclusion on The Nasdaq Global Select Market. On each of March 2, 2022 and May 24, 2022, we received a deficiency letter from Nasdaq notifying us that, for 30 consecutive business days, the bid price of our common stock had closed below the $ 1. 00 per share minimum bid price requirement for continued inclusion on The Nasdaq Global Select Market pursuant to Nasdaq ~~Listing~~ **98Listing** Rule 5450 (a) (1), or the Bid Price Requirement. We were provided a period of 180 calendar days to regain compliance with the Bid Price Requirement, and in each case, we regained compliance within the cure period, including in the second instance by implementing a reverse stock split of our common stock. On July 6, 2022, we received another deficiency letter from Nasdaq notifying us that we were not in compliance with Nasdaq Listing Rule 5450 (b) (2) (A), or the Minimum MVLS Requirement, for continued listing on The Nasdaq Global Select Market, as the market value of our common stock was less than $ 50, 000, 000 for the previous 30 consecutive business days. Nasdaq also noted that we were not in compliance with Nasdaq Listing Rule 5450 (b) (1) (A), as our stockholders' equity was less than $ 10, 000, 000 and Nasdaq Listing Rule 5450 (b) (3) (A), as our total assets and total revenue for the most recently completed fiscal year or for two of the three most recently completed fiscal years were less than $ 50, 000, 000. A company that has its primary equity security listed on The Nasdaq Global Select Market must satisfy at least one of the standards in Nasdaq Listing Rule 5450 (b). On December 5, 2022, we received another deficiency letter from Nasdaq notifying us that we were not in compliance with Nasdaq Listing Rule 5450 (b) (2) (C), or the Minimum MVPHS Requirement, for continued listing on The Nasdaq Global Select Market, as the market value of our publicly held shares was less than $ 15, 000, 000 for each of the previous 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810 (c) (3), we were provided until January 2, 2023 to regain compliance with the Minimum MVLS Requirement and until June 5, 2023 to regain compliance with the Minimum MVPHS Requirement. Alternatively, if we did not regain compliance with the Minimum MVLS Requirement or the Minimum MVPHS Requirement by the applicable compliance date, we were eligible to transfer the listing of our common stock to The Nasdaq Capital Market, provided that we met the applicable requirements for continued listing on The Nasdaq Capital Market. Following the receipt of the proceeds from the second tranche of a private placement in December 2022 and after amending our Loan Agreement to permit a transfer, we applied to transfer the listing of our common stock to The Nasdaq Capital Market. The transfer was approved effective January 11, 2023 following Nasdaq' s determination that we ~~91met --~~ **met** the applicable requirements for continued listing on The Nasdaq Capital Market, including Nasdaq Listing Rule 5550 (b) (1), the minimum stockholders equity requirement for continued listing on The Nasdaq Capital Market. In addition, Nasdaq advised us that, upon the transfer of our listing to The Nasdaq Capital Market, we would be in compliance with Nasdaq Listing Rule 5550 (a) (5), the market value of publicly held shares requirement for continued listing on The Nasdaq Capital Market. Any delisting of our common stock from The Nasdaq Capital Market or a transfer of the listing of our common stock to another nationally recognized stock exchange having listing standards that are less restrictive than The Nasdaq Capital Market, in each case after a specified cure period, are events of default under our Loan Agreement, which could adversely effect our financial condition and ability to pursue our business strategy. 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 certificate of incorporation and our 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 are 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: ● provide for 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; **99** ● limit the manner in which stockholders can remove directors from our board of directors; ● provide for 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 approval of the holders of at least 75 % of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three- years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. An active trading market for our common stock may not be sustained. From July 20, 2017 through January 10, 2023, our common stock traded on The Nasdaq Global Select Market. On January 11, 2023, our common stock began trading on The Nasdaq Capital Market. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price for our common stock and thereby affect your ability to sell your shares. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration. ~~92The~~ -- **The** price of our common stock is volatile and fluctuates substantially, which could result in substantial losses for purchasers of our common stock. Our stock price is volatile and fluctuates substantially. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that 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 common stock. The market price for our common stock may be influenced by many factors, including: ● **results of preclinical studies and clinical trials of KPI- 012 or any other product candidates we may develop; ● our ability to receive marketing approval for and to successfully commercialize KPI- 012 or any other product candidate we may develop; ● results of clinical trials of product candidates of our competitors; ●** whether we receive, and the amount of, any future milestone payments from Alcon in connection with the sale of our Commercial Business; ● ~~our strategic decision to focus our research and development efforts on our MSC- S platform, including KPI- 012; ● results of preclinical studies and clinical trials of KPI- 012 or any other product candidates we may develop; ● our ability to receive marketing approval for and to successfully commercialize KPI- 012 or any other product candidate we may develop; ● results of clinical trials of product candidates of our competitors; ●~~ changes in the structure of healthcare payment systems; ● the success of competitive products or technologies; **100** ● regulatory or legal developments in the United States and other countries; ● developments or disputes concerning patent applications, issued patents or other proprietary rights; ● the recruitment or departure of key scientific, commercial or management personnel; ● the level of expenses related to the development of KPI- 012 and any other product candidate we develop; ● the results of our efforts to discover, develop, acquire or in- license additional products, product candidates or technologies for the treatment of diseases or conditions, 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; ● sales of common stock by us, our executive officers, directors or principal stockholders, or others, or the anticipation of such sales **; ● the concentration of our stock ownership** ; ● variations in our financial results or those of companies that are perceived to be similar to us; ● market conditions in the pharmaceutical and biotechnology sectors; ● the societal and economic impact of public health epidemics, such as the COVID- 19 pandemic; ● general economic, industry and market conditions; ● political instability in the United States and Europe, including as a result of Congress failing to timely raise the U. S. debt ceiling; or ● the other factors described in this " Risk Factors " section. In the past, following periods of volatility in the market price of a company' s securities, securities class- action litigation has often been instituted against that company. We also may face securities class- action litigation if we cannot obtain regulatory approval for or fail to successfully commercialize KPI- 012 or any other product candidate we develop. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management' s attention and resources. ~~93Sale~~ **Sales** of a substantial number of shares of our common stock could cause the market price of our common stock to drop significantly, even if our business is doing well. Sales of a substantial number of shares of our common stock, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March 28, ~~2024~~ **2025** , we had outstanding ~~2~~ **6** , ~~816~~ **452** , ~~454~~ **398** shares of common stock. Shares of our common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act of 1933, as amended, or the Securities Act, or to the extent such shares have already been registered under the Securities Act and are held by non- affiliates of ours. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. In addition, we have filed or intend to file registration statements registering all shares of common stock that we may issue under our equity compensation plans or pursuant to equity awards made to newly hired employees outside of equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. **101In** ~~In December~~ 2022 **, 2023 and 2024** , we sold to certain institutional investors shares of our common stock and **/ or** shares of our ~~Series E Convertible Non- Redeemable Preferred~~ **preferred** ~~Stock~~ **stock** in ~~a~~ private ~~placement~~ **placements** . We have filed ~~a~~ registration ~~statement~~ **statements** on Form S- 3 covering the resale of ~~the~~ **such shares of** common stock ~~held by such investors in the private placement~~ and the common stock issuable upon conversion of the ~~Series E Preferred~~ **preferred** ~~Stock~~ **stock** issued in the private ~~placement~~ **placements** , and we have agreed to keep **each** such registration ~~statement~~ **statements** effective until the date the shares covered by it have been sold or can be resold without restriction under Rule 144 of the Securities Act. ~~In December 2023 and in March 2024, we also sold to certain institutional investors in private placements shares of our Series F Convertible Non- Redeemable Preferred Stock and shares of our Series G Convertible Non- Redeemable Preferred Stock, respectively. We have agreed to register for resale the shares of common stock issuable upon conversion of such preferred stock, upon demand by the~~

~~investors.~~ The sale or resale of these shares in the public market, or the market' s expectation of such sales, may result in an immediate and substantial decline in our stock price. Such a decline ~~will~~ **would** adversely affect our investors and also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. ~~Our~~ **Certain** existing stockholders will experience dilution upon any future conversion of the outstanding shares of our preferred stock into shares of our common stock. Each outstanding share of Series E ~~Convertible Non- Redeemable~~ Preferred Stock, Series F ~~Convertible Non- Redeemable~~ Preferred Stock ~~and~~ **,** Series G ~~Convertible Non- Redeemable~~ **Preferred Stock, Series H Preferred Stock and Series I** Preferred Stock is initially convertible into 100 shares of our common stock at any time at the option of the **applicable** holder, subject to certain beneficial ownership limitations **which prohibit any such conversion if the holder would own, following such conversion, in excess of 9** . ~~Our~~ **99 % of the outstanding shares of our common stock. Such holder of preferred stock can also elect for its beneficial ownership limitation to be increased up to 19. 99 % upon 61 days' notice. Certain** existing stockholders will experience dilution upon any future conversion of the outstanding shares of our ~~Series E Convertible Non- Redeemable Preferred~~ **preferred** ~~Stock~~ **stock** ~~, Series F Convertible Non- Redeemable Preferred Stock or Series G Convertible Non- Redeemable Preferred Stock~~ into shares of our common stock. Our largest stockholder may have the ability to exercise significant influence over certain of our business decisions and could influence matters submitted to stockholders for approval. ~~Entities~~ **Bakers Brothers Life Sciences, L. P. and 667, L. P., which are** ~~affiliated~~ **affiliates** ~~with our largest stockholder~~ **of Baker Bros. Advisors LP, which we refer to collectively as Baker Brothers** owned, in the aggregate, shares of common stock representing approximately ~~9~~ **18** . ~~47~~ **63** % of our outstanding common stock as of March 28, ~~2024~~ **2025** . Such stockholder also holds all of the outstanding shares of our Series E ~~Convertible Non- Redeemable~~ Preferred Stock, ~~the~~ Series F ~~Convertible Non- Redeemable~~ Preferred Stock and ~~the~~ Series G ~~Convertible Non- Redeemable~~ Preferred Stock **, and 35** . **87 %** ~~94Pursuant to the terms~~ of the ~~certificates of designation governing our~~ outstanding shares of **our Series H** ~~preferred~~ **Preferred** ~~stock~~ **Stock** ~~, such stockholder can elect to convert its shares of preferred stock into shares of common stock at any time, provided that it would not own, following such conversion, in excess of 9. 99 % of the outstanding shares of our common stock~~ . Such stockholder **could** ~~can also~~ elect **,** ~~for its beneficial ownership limitation to be increased up to 19. 99 %~~ upon 61 days' notice **to us,** ~~. If such stockholder elects~~ to convert **a portion of** its shares of preferred stock into common stock **, up to the** ~~and / or increase its~~ beneficial ownership ~~limitations~~ **limitation of** ~~to up to~~ 19. 99 % ~~, it would~~ **. Baker Brothers** ~~hold~~ **holds** a significant percentage of our outstanding shares of common stock and could exercise significant influence **over** matters submitted to our stockholders for approval. In addition, pursuant to the terms of our securities purchase agreements for the **2022, 2023 and March 2024** private placement transactions, we have agreed that we will not, without the prior approval of ~~such stockholder~~ **Baker Brothers** (1) issue or authorize the issuance of any equity security that is senior or pari passu to the Series E ~~Convertible Non- Redeemable~~ Preferred Stock, the Series F ~~Convertible Non- Redeemable~~ Preferred Stock or the Series G ~~Convertible Non- Redeemable~~ Preferred Stock with respect to liquidation preference, (2) incur any additional indebtedness for borrowed money in excess of $ 1. 0 million, in the aggregate, outside the ordinary course of business, subject to specified exceptions, including the refinancing of our existing indebtedness or (3) pay or declare any dividend or make any distribution on, any of our shares of capital stock, subject to specified exceptions. **Additionally, pursuant to the terms of our securities purchase agreement for the June 2024 private placement transaction, we have agreed that we will not, without the prior approval of the stockholders holding two- thirds of the outstanding shares of Series H Preferred Stock, issue or authorize the issuance of any equity security that is senior or pari passu to the Series H Preferred Stock with respect to liquidation preference.** As a holder of our Series E Preferred Stock, ~~the stockholder~~ **Baker Brothers** has the right to have our board of directors nominate and recommend for election by the stockholders up to three designees to our board of directors, subject to certain requirements and exceptions. In addition, as a holder of our Series E Preferred Stock, ~~such stockholder~~ **Baker Brothers** has certain rights to participate in our future equity offerings, which rights are more fully described in Item 1, " Business " of our Annual Report on Form 10- K for the year ended December 31, ~~2023~~ **2024** . As a result of the foregoing, **Baker Brothers** ~~our largest stockholder~~ may have the ability to exercise significant influence over certain matters affecting our business. Such stockholder may have interests that differ from your interests, and it may vote as a stockholder or act in a way with which you disagree and that may be adverse to your interests. ~~The concentration of ownership of~~ **This significant influence could delay, defer,** ~~our~~ **or** ~~capital stock may have the effect of delaying, preventing~~ **prevent** ~~or deterring~~ a change of control ~~of~~ **, merger, consolidation,** ~~our~~ **or** ~~company~~ **sale of all or substantially all of our assets that our other stockholders support** . **or conversely this significant influence** could ~~deprive~~ **result in the consummation of such a transaction that** our **other** stockholders ~~of an opportunity to receive~~ **do not support. This significant influence could also discourage** a ~~premium for their~~ **potential investor from acquiring our** common stock ~~as part~~ **due to the limited voting power** of ~~a sale of our company~~ **such stock relative to the common stock held by 102Baker Brothers** and may adversely affect the market price of our common stock **and, in turn, the market value of our common stock for Nasdaq listing purposes** . 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, " as defined in Rule 12b- 2 under the Securities Exchange Act of 1934, as amended **, or the Exchange Act** . We would cease to be a smaller reporting company if we have a public float in excess of $ 250 million or have annual revenues in excess of $ 100 million and a public float in excess of $ 700 million, determined on an annual basis. As a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies. These exemptions include: ● not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting; ● reduced disclosure obligations regarding executive compensation; ● being permitted to provide only two years of audited financial statements in our annual report on Form 10- K, with correspondingly reduced " Management' s Discussion and Analysis of Financial Condition and Results of Operations " disclosure; and ● not being required to furnish a stock performance graph in our annual report. We cannot predict whether investors will find our common stock less

attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. ~~95We~~ **We** have incurred and will continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices. As a public company, and particularly since we ceased being an " emerging growth company ", we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes- Oxley Act of 2002, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Capital Market 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 devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs relative to prior years and will make some activities more time- consuming and costly. For as long as we remain a smaller reporting company, we may take advantage of certain exemptions from various reporting requirements as described in the preceding risk factor. Pursuant to Section 404 of the Sarbanes- Oxley Act of 2002, 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 and a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If ~~we~~ **103we** 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 financial statements. 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. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our Loan Agreement and our securities purchase agreements ~~entered into with certain institutional investors~~ for our 2022, 2023 and **March** 2024 private placements restrict us from paying dividends. 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. Our certificate of incorporation designates the state courts in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors, officers and employees. Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws or as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware, or any action asserting a claim against us governed by the internal affairs doctrine. We do not expect this choice of forum provision will apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which federal courts have exclusive jurisdiction. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur ~~96~~ **additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and operating results. General Risk FactorsChanges in tax laws or in their implementation or interpretation could adversely affect our business and financial condition. Changes in tax law may adversely affect our business or financial condition. The 2017 Tax Act, as amended by the CARES Act, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35 % to a flat rate of 21 % and the limitation of the deduction for NOLs to 80 % of current year taxable income for losses arising in taxable years beginning after December 31, 2017 (though any such NOLs may be carried forward indefinitely). In addition, beginning in 2022, the 2017 Tax Act eliminates the option to deduct research and development expenditures currently and requires corporations to capitalize and amortize them over five years or 15 years for expenditures attributable to foreign research. In addition to the CARES Act, as part of Congress' s response to the COVID- 19 pandemic, economic relief legislation was enacted in 2020 and 2021 containing tax provisions. The IRA was also signed into law in August 2022. The IRA introduced new tax provisions, including a one percent excise tax imposed on certain stock repurchases by publicly traded companies. The one percent excise tax generally applies to any acquisition of stock by the publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for money or other property (other than stock of the company itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. Regulatory guidance under the 2017 Tax Act, the IRA, and such additional legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial 104**