Risk Factors Comparison 2025-02-28 to 2024-03-22 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10- K, including our financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. Risks Related to Our Financial Position and Capital Needs We are a clinical- stage biopharmaceutical company with no approved products and a limited operating history. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability. We are a clinical stage biopharmaceutical company with no approved products and a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and clinical trials of our product candidates, securing related intellectual property rights and conducting discovery, research and development activities for our programs. As a result, we are not profitable and have incurred losses in each period since our inception in 2011. For the years ended December 31, ~~2022 and~~ 2023 **and 2024** , we reported a net loss of $ ~~64. 9 million and $~~ 81. 6 million **and $ 43. 5 million** , respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~369~~ **412** . ~~3~~ **8** million. We expect to continue to incur significant losses for the foreseeable future. We anticipate that our expenses will increase substantially if, and as, we: ● pursue the clinical and preclinical development of our current and future product candidates; ● leverage our technologies to advance product candidates into preclinical and clinical development; ● seek regulatory approvals for product candidates that successfully complete clinical trials, if any; ● attract, hire, and retain additional clinical, quality control and scientific personnel; ● expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; ● establish our manufacturing capabilities through third parties or by ourselves and scale- up manufacturing to provide adequate supply for clinical trials and commercialization; ● expand and protect our intellectual property portfolio; ● establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly; ● acquire or in- license other product candidates and technologies. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates and we may never generate revenue that is significant or large enough to achieve profitability. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Accordingly, our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment. **There is substantial doubt regarding our ability to continue as a going concern.** We **will need to raise substantial additional funding, which may not be available on acceptable terms, if at all, to be able to continue as a going concern and advance any our product candidates. Failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or other operations. Raising additional capital may dilute our existing shareholders, restrict our operations or cause us to relinquish valuable rights. There is substantial doubt regarding our ability to continue as a going concern. Our continued existence is dependent upon our ability to obtain additional capital. As of December 31, 2024, we had cash, cash equivalents and restricted cash of approximately $ 39. 9 million. In February 2025, we received a payment of $ 19. 8 million related to receivables from Austrian research incentive program. Our management believes that such cash, cash equivalents and restricted cash will not be sufficient to fund our operating expenses and capital requirements for one year after the date that the financial statements are issued, whether or not we curtail efforts with respect to certain of our product candidates. We will require significant additional funding to advance any of our product candidates beyond the short term. We are seeking funds through collaborations, strategic alliances, or licensing arrangements with third parties, and such agreements may impact rights to our product candidates or technologies, future revenue streams, research programs or products candidates or to grant licenses on terms that may not be favorable to us. Such arrangements will limit our participation in the success of any of our product candidates that receive regulatory approval. We may also seek to raise such capital through public or private equity, royalty financing or debt financing. Raising funds in the current economic environment is challenging and financing may not be available in sufficient amounts or on acceptable terms, if at all. The issuance of additional securities, whether equity or debt, or the possibility**

of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities may dilute the ownership of existing shareholders. Incurring debt would result in increased fixed payment obligations, and we may agree to restrictive covenants, such as limitations on our ability to incur additional debt or limitations on our ability to acquire, sell or license intellectual property rights that could impede our ability to conduct our business. 57We will require substantial additional financing and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our non- replicating and replicating technologies and our product candidates derived from these technologies. Preclinical studies and clinical trials and additional research and development activities will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the development of our current product candidates and programs, any future product candidates we may choose to pursue, when we begin to develop our own manufacturing capabilities and other corporate uses. These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals, and manufacturing and supply, as well as marketing and selling any products approved for sale. Our expenses could increase beyond our current expectations if other unanticipated costs arise or if the FDA, the EMA, or other comparable foreign regulatory authorities requires us to perform clinical trials and other studies in addition to those that we currently anticipate. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current or future product candidates. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or terminate our research and development programs or future commercialization efforts. As of December 31, ~~2023~~ **2024** , we had $ ~~117~~ **39** . ~~5~~ **9** million in cash, cash equivalents and restricted cash. **Our management believes** ~~Based on our research and development plans, we expect~~ that **such** ~~our existing~~ cash ~~and ,~~ cash equivalents **and restricted cash** ~~at December 31, 2023, together with the payment we expect to receive prior to the termination of the Roche Collaboration Agreement in April 2024,~~ will ~~63enable us~~ **not be sufficient** to fund our operating expenses and capital ~~expenditure~~ requirements for ~~at least the next 12 months. This estimate is based on~~ **one** ~~assumptions that may prove to be wrong~~ **year after the date the financial statements are issued** , **whether** ~~and we could use our~~ **or not** ~~available capital resources sooner than~~ we **curtail efforts with** ~~expect~~ **respect** ~~. Changes may~~ **to certain of** ~~occur~~ **our current and future product candidates. We will require significant additional funding to advance any of our product candidates** beyond **the short term** ~~our control that would cause us to consume our available capital before that time, including changes in~~ and ~~progress of~~ **to sustain** our **operations** ~~development activities and changes in regulation~~ . Our future capital requirements depend on many factors, including: ● the scope, progress, results and costs of researching and developing our current and future product candidates and programs, and of conducting preclinical studies and clinical trials; ● the number and development requirements of other product candidates that we may pursue, and other indications for our current product candidates that we may pursue; ● our ability to achieve efficiencies and expected cost reductions in connection with our recent strategic refocus; ● the stability, scale and yields of our future manufacturing process as we scaleup production and formulation of our product candidates for later stages of development and commercialization; ● the timing of, and the costs involved in, obtaining regulatory and marketing approvals and developing our ability to establish sales and marketing capabilities, if any, for our current and future product candidates we develop if clinical trials are successful; ● the success of our collaborations with Gilead; ● our ability to establish and maintain collaborations, strategic licensing or other arrangements and the financial terms of such agreements. For example, in January 2024 Roche notified us of their decision to terminate their collaboration agreement with us; ● the cost of commercialization activities for our current and future product candidates that we may develop, whether alone or with a collaborator; ● the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; **58** ● the timing, receipt and amount of sales of, or royalties on, our future products, if any; and ● the emergence of competing oncology and infectious disease therapies and other adverse market developments. Other than the Stock Purchase Agreement and our collaboration agreements with Gilead, we do not have any committed external source of funds or other support for our development efforts. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights. Until we can generate sufficient product and royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements and grant funding. If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ~~64ownership~~ **ownership** interest will be diluted. For example, in December 2023 we entered into an Amended and Restated Stock Purchase Agreement with Gilead pursuant to which we issued and sold 15, 000, 000 shares of unregistered common stock to Gilead for approximately $ 21. 25 million, and we may require Gilead to purchase up to approximately $ 8. 75 million of additional share of common stock. In addition, in May 2023 we completed a public offering in which we issued and sold 22, 900, 768 shares of common stock and 15, 268 shares of Series A- 2 convertible preferred stock, which are convertible into common stock on a 1, 000 to one basis, pursuant to our shelf registration statement on Form S- 3 (File No. 333- 266104) for net proceeds of $ 46. 3 million. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs 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, reduce or terminate our product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves. If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders if we issue equity securities, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may evaluate various acquisitions and strategic partnerships, including acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including: ● increased operating expenses and cash requirements; ● the assumption of additional indebtedness or contingent liabilities; ● the issuance of our equity securities; ● assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integration; **59** ● the diversion of our management' s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition; ● retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; ● risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and ● our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition. In addition, if we undertake acquisitions, we may incur large one- time expenses and acquire intangible assets that could result in significant future amortization expense. ~~65We~~ **We** have obtained funding from an agency of the Austrian government that contains certain covenants that may restrict our operations. In the past, we have contracted numerous funding agreements with an agency of the Austrian government to partially finance our research and development programs, such as personnel costs, material costs, third- party services, travel expenses and research and development infrastructure use. These funding agreements include both below market rate loans and grants, which are subject to various criteria linked to certain terms and conditions as well as certain costs attributable to the respective funded research and development program. We have committed to reporting obligations and to obtain the approval for significant changes in the cost structure of the funded research and development programs. If we were to breach these contractual obligations, we may be held liable by the agency of the Austrian government for damages incurred by such agencies resulting from the breach of contract and we could be required to reimburse in full the funding granted by such agencies. **As of December 31, 2024, we have no outstanding loans related to these funding agreements. A final principal repayment of $ 1. 1 million was made in the year ended December 31, 2024.** Further, pursuant to the general terms of each grant, the agency is entitled to re- evaluate the funding granted to us in case of a fundamental change in our ownership structure if such change no longer ensures that the purpose of the funding can be achieved. Any such re- evaluation could negatively impact the funding that we receive or have received from the agency or that we may receive in the future from other agencies of the Austrian government. Risks Related to Our Business and IndustryIf we are unable to advance our current or future product candidates into and through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed. All of our product candidates are in early stages of development, including our lead product candidate, **eseba- vec (formerly** HB- 200 **)** ~~, which is currently in a Phase 1 / 2 clinical trial~~ , and as such will require extensive preclinical and clinical testing. We cannot predict with any certainty if or when we might submit an IND, or BLA, or comparable foreign applications, for regulatory approval for any of our product candidates or whether any such IND or BLA, or comparable foreign applications, will be accepted for review by the FDA or comparable foreign regulatory authority, or subsequently whether any such IND will go into effect or BLA will be approved upon review, or whether comparable foreign applications will fulfill the related milestones. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. For example, **in 2024** we ~~recently~~ announced a strategic refocus to prioritize ~~clinical development of~~ HB- **700** ~~200 for the treatment of HPV16 head and neck cancers~~ and Gilead- partnered programs in infectious disease and to pause development activities related to HB- 300 and most other preclinical research activities. In connection with this strategic refocus, we implemented an approximately 30 % ~~reduction~~ **60reduction** in our workforce and discontinued our GMP manufacturing facility project. In ~~addition, in~~ January 2024 Roche notified us of their decision to terminate the collaboration and licensing agreement for HB- 700 in KRAS mutated cancers, despite acknowledging we had met all go- forward criteria under the agreement. Our ability to generate product revenues, which we do not expect to occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the product candidates we develop, which may never occur. Before we are able to generate any revenues from product sales, our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts. The success of our current and future product candidates will depend on several factors, including the following: ● successful completion of preclinical studies and clinical trials; ~~66~~ ● sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials; ● acceptance of INDs and comparable foreign applications for our planned clinical trials or future clinical trials; ● successful enrollment and completion of clinical trials; ● successful data from our clinical program that support an acceptable risk- benefit profile of our product candidates in the intended populations; ● receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities; ● scale- up of our manufacturing processes and formulation of our product candidates for later stages of development and commercialization; ● establishing our own manufacturing capabilities or agreements with third- party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidates are approved; ● entry into collaborations to further the development of our product candidates; ● obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates; ● successfully launching commercial sales of our product candidates, if and

when approved; ● acceptance of the product candidate' s benefits and uses, if and when approved, by patients, the medical community and third- party payors; ● the prevalence and severity of adverse events experienced with our product candidates; ● maintaining a continued acceptable safety profile of the product candidates following approval; ● effectively competing with other therapies; ● obtaining and maintaining healthcare coverage and adequate reimbursement from third- party payors; ~~and~~ **and61** ● qualifying for, maintaining, enforcing and defending intellectual property rights and claims. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. The regulatory approval processes of the FDA, the EMA and the European Commission and other comparable foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. The time required to obtain approval from the FDA, the European Commission and other comparable foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval ~~67policies~~ -- **policies** , regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that none of our current or future product candidates will ever obtain regulatory approval. Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following: ● the FDA, the EMA or other comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; ● we may be unable to demonstrate to the satisfaction of the FDA, the EMA or the European Commission or other comparable foreign regulatory authorities that a product candidate is safe, pure and potent or effective for its proposed indication; ● the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA and the European Commission or other comparable foreign regulatory authorities for approval; ● we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; ● the FDA, the EMA or the European Commission or other comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies; ● the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA, or similar foreign submission to the EMA or other comparable foreign regulatory authority, or to obtain approval in the United States, the European Union or elsewhere; ● the supply or quality of materials for product candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate; ● the FDA, the EMA the European Commission, competent authorities of EU Member States or other comparable foreign regulatory authorities may, as applicable, find deficiencies with or fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; ~~and~~ **and62** ● the approval policies or regulations of the FDA, the EMA and the European Commission or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, results of operations and prospects. We have conducted, and intend to conduct, clinical trials of certain of our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA, including compliance with all applicable U. S. laws and regulations. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with GCP, including review and approval by an independent ethics committee and informed consent from subjects. The study population must also adequately represent the U. S. population, and the data must be applicable to the U. S. population and U. S. medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. There can be no assurance the FDA will accept data from trials ~~68conducted~~ -- **conducted** outside of the United States. Comparable risks apply abroad in relation to the data that was generated in the United States which we intend to leverage for purposes of obtaining regulatory authorizations abroad. There can be no assurance that foreign regulatory authorities will accept data from trials conducted outside of their territory. The FDA, the EMA and the European Commission and other comparable foreign regulatory authorities have discretion in the approval process and determining when or whether regulatory approval will be obtained for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the European Commission or any other comparable foreign regulatory authorities. Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. Our clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization. Before obtaining regulatory approvals for the commercial sale of our product candidates, including ~~HB~~ **eseba** - ~~200~~ **vec** , HB- 400, HB- 500, HB- 700 and any other future product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and, because our product candidates are in an early

stage of development, there is a high risk of failure and we may never succeed in developing marketable products. Clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. ~~Any~~ **63Any** inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future drug sales and regulatory and commercialization milestones. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects. Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA, the EMA and the European Commission, or other comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA, the EMA and the European Commission or other comparable foreign regulatory authorities will view our product candidates as having efficacy even if positive results are observed in our clinical trials. To the extent that the results of the trials are not satisfactory to the FDA, the EMA and the European Commission or other comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. ~~69Our~~ -- **Our** preclinical programs may experience delays or our product candidates may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these product candidates on a timely basis or at all, which would have an adverse effect on our business. Certain of our product candidates and all of our next generation product candidates are still in the preclinical development stage, and the risk of failure of preclinical programs is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies to obtain regulatory clearance to initiate human clinical trials, including based on INDs in the United States and clinical trial applications in Europe. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA, the competent authorities of EU Member States or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our product candidates. As a result, we cannot be sure that submission of INDs or similar applications will result in the FDA, the competent authorities of EU Member States or other comparable foreign regulatory authorities allowing clinical trials to begin. We have in the past, and may in the future, encounter challenges in collecting, transporting and analyzing clinical blood samples, which could cause delays or prevent the approval of our drug candidates. Interim, top line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to regulatory audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim, top line or preliminary data from our clinical trials. We may decide to conduct an interim analysis of the data after a certain number or percentage of patients have been enrolled, or after only a part of the full follow- up period but before completion of the trial. Similarly, we may report top line or preliminary results of primary and key secondary endpoints before the final trial results are completed. Preliminary, top line and interim data from our clinical trials may change as more patient data or analyses become available. Preliminary, top line or interim data from our clinical trials are not necessarily predictive of final results and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available, and we issue our final clinical trial report. These data also remain subject to verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary, interim and top line data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects. Further, others, including regulatory agencies, may not accept or agree with our interim, topline or preliminary analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular ~~program~~ **64program**, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. Results of earlier studies and trials of our product candidates may not be predictive of future trial results. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Even if we are able to commence clinical trials, issues may arise that could suspend or terminate such clinical trials. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies, including our oncology mouse studies and animal studies, may not be predictive of the results of outcomes in human clinical trials. For example, our oncology product candidates that are in preclinical development may demonstrate different chemical and ~~70biological~~ -- **biological** properties in patients than they do in

laboratory animal studies or may interact with human biological systems in unforeseen or harmful ways. Our replicating technology is early in clinical development and could therefore prove to be unsafe. Our replicating technology is an attenuated viral vector technology ~~which is in a Phase 1 / 2 clinical trial~~. If our **technology** ~~ongoing Phase 1 / 2 clinical trial for HB- 200~~ causes unexpected side effects that are not tolerable in the treatment of the relevant patient group, the further development of the product candidate and any other potential products based on the replicating technology may be significantly limited or become impossible. Although clinical trials of onco- viral therapies have supported their role as a potential treatment for cancer, there is the risk of uncontrolled replication in vivo and possible transmission to patients' contacts, such as other patients and health care workers. In recent years, clinical trials to address these concerns have been conducted. Any such transmission by our product candidates or a competitor would have an adverse impact on our future research and development efforts. Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development. We have concentrated all of our research and development efforts on product candidates based on our non- replicating and replicating technologies, and our future success depends on the successful development of this therapeutic approach. Our non- replicating and replicating technologies utilize arenaviruses to activate CD8 T cells and induce pathogen- neutralizing antibodies. There are no approved products that utilize the arenavirus. Because our non- replicating and replicating technologies are novel, regulatory agencies may lack experience with product candidates which may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. We have not yet succeeded and may not succeed in demonstrating safety and efficacy for any of our product candidates in ongoing or late- stage clinical trials or in obtaining marketing approval thereafter. In addition, our vectors are live, gene-modified organisms for which the FDA, the EU and other comparable foreign regulatory authorities and other public health authorities, such as the Centers of Disease Control and Prevention and hospitals involved in clinical studies, have established additional safety and contagion rules and procedures, which could establish additional hurdles for the development, manufacture or use of our vectors. These hurdles may lead to delays in the conduct of clinical trials or in obtaining regulatory approvals for further development, manufacturing or commercialization of our product candidates. We may also experience delays in transferring our process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. ~~Since~~ **65Since** the number of patients that we plan to dose in some of our planned clinical trials is small, the results from such clinical trials, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates. A trial design that is considered appropriate for regulatory approval includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. ~~In the Phase 2 portion of our Phase 1 / 2 trial for HB - 200 in combination with pembrolizumab, we expect to enroll two groups of 10 to 20 patients each.~~ Future trials ~~for HB - 200~~ **of eseba- vec** or other product candidates may similarly enroll a small number of patients although some trials will require the enrollment of more patients. The preliminary results of trials with smaller sample sizes can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, making the trial results less reliable than trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials, we may not achieve a statistically significant result or the same level of statistical significance, if any, that would have been possible to achieve in a larger trial. ~~71Our~~ -- **Our** product candidates may cause serious adverse events, undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential or result in significant negative consequences. Undesirable side effects caused by our product candidates could cause us or regulatory authorities, including IRBs or ethics committees, to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the European Commission or other comparable foreign regulatory authorities. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the drug. Because of our dose escalation design for our clinical trials, undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. If we do observe severe side effects in our clinical trials, our ongoing clinical trials may be halted or put on clinical hold prior to completion if there is an unacceptable safety risk for patients. If unacceptable toxicities arise in the development of our product candidates, we could suspend or terminate our trials or the FDA, the competent authorities of EU Member States or other comparable foreign regulatory authorities, or local regulatory authorities such as IRBs or ethics committees, could order us to cease clinical trials. Competent national health authorities, such as the FDA or the European Commission, could also deny approval of our product candidates for any or all targeted indications. Even if the side effects presented do not preclude the product from obtaining or maintaining marketing approval, treatment- related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates, if approved, to understand the side effect profile of these technologies for both our planned clinical trials and upon any commercialization of any product candidates, if approved. Inadequate training in recognizing or managing the potential side effects of our technologies could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who

remain in the trial until its conclusion. The enrollment of patients depends on many factors, including: ● the patient eligibility criteria defined in the protocol; ● the size of the patient population required for analysis of the trial' s primary endpoints; **66** ● the proximity of patients to trial sites; ● the design of the trial; ● our ability to recruit clinical trial investigators with the appropriate competencies and experience; ● clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating; ● the novel nature of the technology underlying our product candidates which may not be known to or be negatively perceived by clinical trial investigators or patients; ~~72~~ ● our ability to obtain and maintain patient consents; ● the risk that patients enrolled in clinical trials will drop out of the trials before the manufacturing and infusion of our product candidates or trial completion; and ● current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e. g. the recent COVID- 19 pandemic). In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates or similar areas, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for the treatment of infectious diseases and cancers, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and hematopoietic stem cell transplantation, rather than enroll patients in any future clinical trial. Additionally, because some of our clinical trials will be in patients with relapsed or refractory cancer, the patients are typically in the late stages of the disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the trial and requiring additional enrollment. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these trials and adversely affect our ability to advance the development of our product candidates. We have limited experience as a company conducting clinical trials. We have limited experience as a company in conducting clinical trials. In part because of this lack of experience, we cannot be certain that our ongoing clinical trials will be completed on time or if our planned clinical trials will begin at all. Large scale trials would require significant additional financial and management resources and reliance on third- party clinical investigators, contract research organizations (CROs), or consultants. Relying on third- party clinical investigators or CROs may force us to encounter delays that are outside of our control. The market opportunities for our oncology product candidates may be limited to those patients who are ineligible for or have failed prior treatments. Cancer therapies are characterized as first line, second line, or third line, and the FDA and comparable foreign regulatory authorities often approve new therapies initially only for a particular line of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, antibody drugs, tumor- targeted small molecules, hormone therapy, radiation ~~therapy~~ **67therapy**, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor- targeted small molecules, or a combination of these. Third line therapies can include hematopoietic stem cell transplantation in certain cancers, chemotherapy, antibody drugs, and small molecule tumor- targeted therapies, more invasive forms of surgery, and new revolutionary technologies. We expect to initially seek approval of our product candidates in most instances at least as a third line therapy, for use in patients with relapsed or refractory metastatic cancer. Subsequently, for those product candidates that prove to be sufficiently safe and beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved as a third or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. ~~73If~~ **If** the market opportunities for our product candidates are smaller than we believe they are, even assuming approval of a drug candidate, our business may suffer. Our projections of both the number of people who have the infectious diseases and cancers we are targeting, as well as the subset of people with these infectious diseases and cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, commissioned reports, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates within our addressable patient population, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as first or second line therapy. Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community. The use of an arenavirus for the treatment of infectious diseases and tumors is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether our product candidates, if approved, are accepted in the market, including: ● the clinical indications for which our product candidates are approved; ● physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment; ● the potential and perceived advantages of our product candidates over alternative treatments; ● the prevalence and severity of any side effects; ● the prevalence and severity of any side effects for virus- based therapeutic products, in particular, other prime- boost therapies; ● product labeling or product insert requirements of the FDA or other regulatory authorities; ● limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory authorities; ● the timing of market introduction of our

product candidates as well as competitive products; **68** ● the cost of treatment in relation to alternative treatments; ● the availability of adequate coverage, reimbursement and pricing by third- party payors and government authorities; ● relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and ● the effectiveness of our sales and marketing efforts. ~~74In~~ **In** addition, although we are not utilizing fully replication competent live virus vectors, our replicating technology uses a replication attenuated vector and adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective may limit market acceptance of our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers, third- party payors or others in the medical community, we will not be able to generate significant revenue and we may not become profitable. Even if we, or any future collaborators, are able to commercialize any product candidate that we, or they, develop, the product may become subject to unfavorable pricing laws, regulations or third- party payor coverage and reimbursement policies, any of which could harm our business. In the United States and markets in other countries, patients generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. These third- party payors decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford many types of treatments. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third- party payors. See " Item 1. Business – Government Regulation – Coverage and Reimbursement. " Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price (ASP), and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Additionally, we, or our collaborators may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we may seek for our product candidates. While we have not yet developed ~~any~~ **69any** companion diagnostic tests for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. In addition, the requirements governing drug pricing vary widely from country to country. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. ~~75Moreover --~~ **Moreover** , in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost- effectiveness of our products to other available therapies. This Health Technology Assessment (" HTA ") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U. S. and generally prices tend to be significantly lower. We cannot predict whether we will receive reimbursement from third- party payors for any product we may successfully commercialize in the future. Any reimbursement we may receive might not be adequate for use to generate significant revenue and we may not become profitable. We are developing, and in the future may develop, other product candidates, in combination with other therapies, which exposes us to additional risks. Our ~~HB~~ **eseba** - ~~200~~ **vec** program is being developed to be used in combination with or without an approved checkpoint inhibitor, a currently approved cancer therapy. In the future, we may develop other product candidates to be used with one or more currently approved cancer therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States

could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially. In addition, if the results from our combination trials are not significantly better than results from the existing therapy that we are combining with, then regulatory authorities, clinical investigators, physicians and patients may perceive our product candidates negatively, which could adversely affect enrollment in our clinical trials, approval by regulatory authorities or commercial adoption of our product candidates, if approved. We may also evaluate our future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval. ~~Negative~~ **70Negative** developments in the field of immuno- oncology and virus- based therapies could damage public perception of any of our product candidates and negatively affect our business. The commercial success of product candidates based on our replicating technology will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in the ~~HB~~ **eseba** - ~~200~~ **vec** program or our other product candidates based on our replicating technology or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno- oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for any product candidates based on our replicating technology that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not ~~76be~~ **be** accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. In addition, responses by national or state governments to negative public perception may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, prospects and results of operations and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. As a result, we may not be able to continue or may be delayed in conducting our development programs. Our product candidates consist of a modified virus. Adverse developments in clinical trials of other immunotherapy products based on viruses, like oncolytic viruses, may result in a disproportionately negative effect for our non- replicating and replicating technologies as compared to other products in the field of infectious disease and immuno- oncology that are not based on viruses. Future negative developments in the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our product candidates. We may not be successful in our efforts to identify and successfully commercialize additional product candidates. Part of our strategy involves identifying novel product candidates. We have developed a pipeline of product candidates and intend to pursue clinical development of additional product candidates utilizing our non- replicating and replicating technologies. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also: ● we may not be able to assemble sufficient resources to acquire or discover additional product candidates; ● competitors may develop alternatives that render our potential product candidates obsolete or less attractive; ● potential product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights; ● potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance; ● potential product candidates may not be effective in treating their targeted diseases or symptoms; ● the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable; **71** ● a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or ● the regulatory pathway for a potential product candidate is highly complex and difficult to navigate successfully or economically. Developing, obtaining regulatory approval for and commercializing additional product candidates will require substantial additional funding and is prone to the risks of failure inherent in medical product development. We cannot provide you with any assurance that we will be able to successfully advance any of these additional product candidates through the development process. ~~77We~~ **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. We may choose to focus our efforts on and allocate resources to a potential product candidate that ultimately proves to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we are unable to evaluate the commercial potential or target market for a particular product candidate, identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position. We face significant competition from

other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other products or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in- license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement. In immuno- oncology for HPV16 **and mutated KRAS** cancers, we face competition from companies such as BioNtech AG, Cue Biopharma, Inc., ~~ISA Pharmaceuticals B. V., in collaboration with Regeneron Pharmaceuticals, Inc., Kite Pharma, a Gilead company, and~~ PDS Biotechnology Corporation **and Elicio Therapeutics Inc**. Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. In addition, other immuno- oncology companies are developing the following technologies, including, but not limited to, neoantigens, bispecific antibodies, engineered cell therapies and tumor specific antigens in areas outside of HPV16 cancers. ~~We~~ **72We** may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. ~~78If~~ **If** product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ● our inability to commercialize any product candidate; ● decreased demand for our product candidates or products that we may develop; ● reputational damage; ● withdrawal of clinical trial participants and inability to continue clinical trials; ● initiation of investigations by regulators; ● costs to defend the related litigation; ● a diversion of management' s time and our resources; ● substantial monetary awards to trial participants or patients; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● loss of revenue; ● exhaustion of any available insurance and our capital resources; and ● a decline in our share price. Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. In the future, we may be unable to maintain this insurance coverage, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. ~~A~~ **73A** variety of risks associated with operating our business internationally could materially adversely affect our business. Many of our employees and a significant portion of our operations are located outside the United States, including in Vienna, Austria. In addition, we plan to seek regulatory approval of our product candidates outside of the ~~79United~~ -- **United** States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including: ● differing regulatory requirements in foreign countries; ● unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements; ● economic weakness, including inflation, or political instability in particular foreign economies and markets; ● compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad; ● foreign taxes, including withholding of payroll taxes; ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; ● difficulties staffing and managing foreign operations; ● workforce uncertainty in countries where labor unrest is more common than in the United States; ● potential liability under the Foreign Corrupt Practices Act of 1977 (FCPA), Office of Foreign Assets Control Anti- Money Laundering Program as required by the Bank Secrecy Act and its implementing regulations, or comparable foreign laws; ● challenges enforcing our contractual

and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; and ● production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad. These and other risks associated with our planned international operations may materially adversely affect our ability to attain or maintain profitable operations. Natural disasters, geopolitical unrest, war, terrorism, public health issues or other catastrophic events could disrupt the supply, delivery or demand of products and reduce our ability to access capital, which could negatively affect our operations and performance. We are subject to the risk of disruption by earthquakes, floods and other natural disasters, fire, power shortages, geopolitical unrest, war, terrorist attacks and other hostile acts, public health issues, epidemics or pandemics and other events beyond our control and the control of the third parties on which we depend. Any of these catastrophic events, whether in the United States, Europe or abroad, may have a strong negative impact on the global economy, our employees, facilities, partners, suppliers, distributors or customers, and could decrease demand for our products, create delays and inefficiencies in our supply chain and make it difficult or impossible for us to continue preclinical studies or clinical trials, seek and receive approval for any of our product candidates by the FDA and comparable foreign regulatory authorities, or deliver products to our customers. Further, disruption of global financial markets and a recession or market correction, including as a result of any resurgence of the coronavirus pandemic, the ongoing military ~~conflict~~ **74conflict** between Russia and Ukraine and the related sanctions imposed against Russia, any escalation of the conflict in Israel and the Gaza Strip, and other global macroeconomic factors, could reduce our ability to access capital, which could, in the future, negatively affect our business. ~~80Our~~ -- **Our** business may be adversely affected by a pandemic, epidemic or outbreak of an infectious disease, such as the recent coronavirus pandemic or other emerging global health threats on business and operations. Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business activities and could cause significant disruption in the operations of third- party contract manufacturers and contract research organizations upon whom we rely, as well as our ability to recruit patients for our clinical trials. For example, the recent coronavirus pandemic had unpredictable impacts on global societies, economies, financial markets, and business practices around the world, and caused temporary delays and disruptions in our clinical development operations. We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue. We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and clinical trials of product candidates, securing related intellectual property rights and conducting discovery, research and development activities for our programs. We intend to develop an in- house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other biotechnology and pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time- consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, there can be no assurance that we will be able to develop inhouse sales and distribution capabilities or establish or maintain relationships with third- party collaborators to commercialize any product in the United States or overseas. Insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, umbrella, and directors' and officers' insurance. Insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. We also expect that firming of the insurance market will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any ~~significant~~ **75significant** uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations. ~~81Exchange~~ -- **Exchange** rate fluctuations may materially affect our results of operations and financial conditions. Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the U. S. dollar and the euro, may adversely affect us. Although we are incorporated in Delaware in the United States, we have significant research and development operations in Austria, and source third- party manufacturing, consulting and other services in the European Union. As a result, our business and the price of our common stock may be affected by fluctuations in foreign exchange rates, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place. Risks Related to Our Reliance on Third PartiesWe are fully dependent on our collaboration with Gilead for the development of our HBV programs, rely on funding from Gilead for development of our human immunodeficiency virus program, and may depend on Gilead or additional third parties for the development and commercialization of our other programs and future product candidates. Our current and future collaborators

may control aspects of our clinical trials, which could result in delays or other obstacles in the commercialization of the product candidates we develop. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidatesWe are currently party to collaborations with Gilead to help expand and advance our pipeline of candidates. In the future, we may form or seek other strategic alliances, joint ventures, or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates we develop. Our current collaborations pose, and potential future collaborations involving our product candidates may pose, the following risks to us: ● collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; ● collaborators may not perform their obligations as expected; ● collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may 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, including technology we in- license, products that compete directly or indirectly with our products or product candidates; ● product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates; ● collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product; **76** ● collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or ~~82invalidate~~ -- **invalidate** our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings; ● collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; ● disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources; ● if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; ● collaboration agreements may restrict our right to independently pursue new product candidates. For example, under the Gilead Collaboration Agreement, we are prohibited from, directly or indirectly, researching, developing, manufacturing or commercializing product candidates targeted to HBV and with respect to HIV so long as Gilead' s option for the program has not expired; and ● collaborations may be terminated by the collaborator (such as the termination of the Roche Collaboration Agreement by Roche), and, if terminated, we may suffer reputational harm, find it more difficult to attract new collaborators and be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. As a result, if we enter into additional collaboration agreements and strategic partnerships, or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to any product candidate we develop could delay the development and commercialization of our other product candidates, which would harm our business prospects, financial condition, and results of operations. We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with additional biotechnology and pharmaceutical companies with respect to development and potential commercialization. Any of these relationships may require us to incur non- recurring and other charges, increase our near and long term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we have entered into or will enter into. For example, in January 2024 Roche notified us of their decision to terminate the Roche Collaboration Agreement despite acknowledging we had met all go- forward criteria under the agreement. We face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex. Whether we reach a definitive agreement for other collaborations 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 progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory ~~authorities~~ **77authorities** 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 ~~83uncertainty~~ -- **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. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to

demonstrate safety and efficacy. We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. For example, under the Restated Gilead Collaboration Agreement, we have granted worldwide exclusive rights to Gilead for using our technologies to develop treatments for HBV, and during the term of the agreement we will be restricted from granting similar rights to other parties. This exclusivity could limit our ability to enter into strategic collaborations with future collaborators. 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. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations or do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. We rely and will continue to rely on third parties to conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates. We depend and will continue to depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners to conduct our preclinical studies and clinical trials under agreements with us. We expect to have to negotiate budgets and contracts with CROs, trial sites and CMOs which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under current good manufacturing practices (cGMP) regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if ~~any~~ **78any** of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. ~~84Any~~ -- **Any** third parties conducting our clinical trials are and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. We rely and expect to continue to rely on third parties to manufacture our clinical product supplies, and we may rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of clinical product supplies or product candidates or fail to do so at acceptable quality levels or prices. We do not currently own any facility that may be used as our clinical- scale manufacturing and processing facility and must currently rely on outside vendors to manufacture our product candidates. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. The manufacture of biological drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up or out, validating the production process and assuring high reliability of the manufacturing process, including the absence of contamination. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including lot consistency, stability of the product, product testing, operator error and availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We have encountered problems with our third party manufacturers in the past, including delays and low yields, and there can be no assurance that we will not encounter similar or other difficulties in the future. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such

manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Our reliance on a limited number of third- party manufacturers exposes us to the following risks: ● the production process for our product candidates is complex and requires specific know- how that only a limited number of CMOs can provide, as a result, we compete with other companies in the field for the scarce capacities of these organizations and may not be able to secure sufficient manufacturing capacity when needed; ● we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA and comparable foreign regulatory authorities must inspect any manufacturers for cGMP compliance as part of our marketing application; **79** ● a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates; ~~85~~ ● a change in manufacturers or certain changes in manufacturing processes / procedures will require that we conduct a manufacturing comparability study to verify that any new manufacturer or manufacturing process / procedure will produce our product candidate according to the specifications previously submitted to the FDA or other regulatory authority, to which we may be unsuccessful; ● manufacturers may have little or no experience with viral vector products and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our product candidates; ● manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any; ● manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately; ● manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products, if any; ● manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign regulatory authorities to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards, of which we have limited control over; ● we may not own, or may have to share, the intellectual property rights to any improvements made by our third- party manufacturers in the manufacturing process for our product candidates; ● manufacturers could breach or terminate their agreements with us; ● raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available timely or may not be suitable or acceptable for use due to material or component defects; ● manufacturers and critical suppliers may be subject to risks related to cyber- attacks that could cause disruptions in manufacturing; ● manufacturers and critical suppliers may be subject to inclement weather, as well as natural or manmade disasters; and ● manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. Any of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA and comparable foreign regulatory authorities, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA and comparable foreign regulatory authorities could place significant restrictions on our company until deficiencies are remedied. ~~Despite~~ **80Despite** our efforts to audit and verify regulatory compliance, one or more of our third- party manufacturing vendors may be found on regulatory inspection by the FDA, competent authorities of EU Member States or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, ~~86including~~ -- **including** shutdown of the third- party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products, if approved, and significantly harm our business, financial condition, results of operations and prospects. If our third- party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations. Risks Related to Government RegulationEven if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a (REMS) in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Comparable foreign regulatory authorities may impose similar requirements. Additionally, under the Food and Drug Omnibus Reform Act of 2022 (FDORA), sponsors of approved drugs and biologics must provide six

months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product' s ability to be marketed. In addition, if the FDA, the European Commission or another comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for any such approved 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 continued compliance with cGMPs and GCPs for any clinical trials that we conduct post- approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or ~~manufacturing~~ **81manufacturing** processes, or our or our distributors', licensees' or co- marketers' failure to comply with changes to regulatory requirements, may result in, among other things: ● restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls; ● fines, warning or untitled letters or holds on clinical trials; ~~87~~ ● suspension of any ongoing clinical trials; ● refusal by the FDA, the European Commission or other comparable foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals; ● product seizure or detention, refusal to permit the import or export of our product candidates, or request that we initiate a product recall; ● injunctions or the imposition of civil or criminal penalties or monetary fines; and ● requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. The FDA' s, the EMA' s and the European Commission and other comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR permits trial sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment of some elements of the application by all EU Member States in which the trial is to be conducted, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State' s decision is communicated to the sponsor through a centralized EU portal, the Clinical Trial Information System, or CTIS. The CTR provides a three- year transition period. The extent to which ongoing clinical trials will be governed by the CTR varies. **As** ~~For clinical trials in relation to which an application for approval was made on the basis~~ of ~~the Clinical Trials Directive before~~ January 31, ~~2023, the CTD will continue to apply on a transitional basis until January 31,~~ 2025 ~~. By that date~~ , all ongoing trials **are** ~~will become~~ subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025. ~~In light of the entry into application of the CTR on January 31, 2022, we may be required to transition clinical trials for which we have obtained regulatory approvals in accordance with the CTD to the regulatory framework of the CTR by October 31, 2024. A transitioning application will need to be submitted to the competent authorities of E. U. Member States through the Clinical Trials Information Systems and related regulatory approval obtained to continue the clinical trial past January 30, 2025. This will require financial, technical and human resources. If we are unable to transition our clinical trials in time, the conduct of those clinical trials may be negatively impacted.~~ We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. If any of these events occurs, our ability to commercialize such product candidate may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could adversely affect our business, financial condition and results of operations. The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown, and may adversely affect our business model. 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 prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability, or the ability of our collaborators, to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other ~~healthcare~~ **82healthcare** reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in ~~88additional~~ -- **additional** downward pressure on the price that we, or our collaborators, may receive for any approved products. See " Business – Other U. S. Healthcare Laws. " We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect: ● the demand for any of our product candidates, if approved; ● the ability to set a price that we believe is fair for any of our product candidates, if approved; ● our ability to generate revenues and achieve or maintain profitability; ● the level of taxes that we are required to pay; and ● the availability of capital. In December 2021, Regulation No 2021 / 2282 on HTA amending Directive 2011 / 24 / EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and **into application on** ~~will apply as of~~ January **12,** 2025 ~~,~~ **. It** is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three- year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health

technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non- clinical (e. g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In light of the fact that the United Kingdom has left the EU, Regulation No 2021 / 2282 on HTA will not apply in the United Kingdom. However, the UK Medicines and Healthcare products Regulation Agency (" MHRA ") is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium (" SMC "), the National Institute for Health and Care Excellence (" NICE "), and the All- Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products. In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation **and on April 10, 2024, the Parliament adopted its related position. The proposed revisions remain to be agreed and adopted by the European Council. In addition, on December 1, 2024, a new European Commission took office. The proposal could, therefore, still be subject to revisions** . If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical and biologic products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. Compliance with new requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may need to change our current manner of operation, which could have a material adverse effect on our ~~business~~ **83business** , financial condition, and results of operations. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Legislative and regulatory proposals may also ~~89impact~~ -- **impact** our regulatory and commercial prospects, expand post- approval requirements, and restrict sales and promotional activities. We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments, whether regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be **, particularly in light of the recent U. S. Presidential and Congressional elections** . Such future price controls or other changes in pricing regulation or negative publicity related to the pricing of pharmaceutical drugs generally could restrict the amount that we are able to charge for our future products, which would adversely affect our anticipated revenue and results of operations. See " Business – U. S. Healthcare Reform. " We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. The FDA or comparable foreign regulatory authorities could require the clearance, CE marking or approval of a companion diagnostic device as a condition of approval for our product candidates. Failure to successfully validate, develop and obtain regulatory clearance or approval for companion diagnostics on a timely basis or at all could harm our drug development strategy. Our success may depend, in part, on the development and commercialization of companion diagnostic tests to select patients for our drug candidates. If safe and effective use of any of our product candidates depends on an in vitro diagnostic that is not otherwise commercially available, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves our product candidates. The process of obtaining or creating such diagnostic is time consuming and costly. Foreign regulatory authorities may impose comparable requirements. Companion diagnostics, which provide information that is essential for the safe and effective use of a corresponding therapeutic product, are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval from therapeutic approval prior to commercialization. The FDA previously has required in vitro companion diagnostics intended to select the patients who will respond to a product candidate to obtain pre- market approval (PMA), simultaneously with approval of the therapeutic candidate. The PMA process, including the gathering of preclinical and clinical data and the submission and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide FDA with reasonable assurance of the device' s safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. After a device is placed on the market, it remains subject to significant regulatory requirements, including requirements governing development, testing, manufacturing, distribution, marketing, promotion, labeling, import, export, record- keeping, and adverse event reporting. We will be subject to additional obligations and regimes with respect to such companion diagnostic tests with regulators outside the United States. In the EEA, companion diagnostics are deemed to be in vitro diagnostic medical devices, or IVDs, and are governed by Regulation 2017 / 746, or IVDR, which entered into application on May 26, 2022, repealing and replacing Directive 98 / 79 / EC. The IVDR defines a companion diagnostic as a device which is essential for the safe and effective use of a corresponding medicinal product to: (a) identify, before and / or during treatment, patients who are most likely

to benefit from the corresponding medicinal product; or (b) identify, before and / or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product. The IVDR and its associated guidance documents and harmonized standards govern, among other things, device design and ~~development~~ **84development**, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post- market surveillance, vigilance, and market surveillance. IVDs, including companion diagnostics, must conform with the general safety and performance requirements, or GSPR, of the IVDR. Compliance with these requirements is a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPR laid down in Annex I to the IVDR, and obtain the right to affix the CE mark, IVD manufacturers must ~~90conduct~~ -- **conduct** a conformity assessment procedure, which varies according to the type of IVD and its classification. Companion diagnostics must undergo a conformity assessment by a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the GSPRs. If the related medicinal product has, or is in the process of, been authorized through the centralized procedure for the authorization of medicinal products, the notified body will, before it can issue a CE Certificate of Conformity, be required to seek a scientific opinion from the EMA on the suitability of the companion diagnostic for use in relation to the medicinal product concerned. For medicinal products that have or are in the process of authorization through any other route provided in EU legislation, the Notified Body must seek the opinion of the national competent authority of an EU Member State. The CE Certificate of Conformity and the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity. Given our limited experience in developing and commercializing diagnostics, we do not plan to develop companion diagnostics internally and thus will be dependent on the sustained cooperation and effort of third- party collaborators in developing and obtaining approval for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval or CE marking for the companion diagnostics, including issues relating to selectivity / specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval or CE marking the companion diagnostics could delay or prevent approval of our product candidates. In addition, we, our collaborators or third parties may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the medical community. If such companion diagnostics fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales, if any, of any product candidate for which we obtain approval and that requires a companion diagnostic test. In addition, any companion diagnostic collaborator or third party with whom we contract may decide not to commercialize or to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates, or our relationship with such collaborator or third party may otherwise terminate. We may not be able to enter into arrangements with another provider to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and / or delay the development or commercialization of our product candidates. We may pursue breakthrough therapy designation from the FDA for our product candidates but such designation may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that our product candidates will receive marketing approval. We may in the future seek breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For compounds 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. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead ~~determine~~ **85determine** not to make such designation. We cannot be sure that any evaluation we may make of our product candidates as qualifying for breakthrough therapy designation will meet the FDA' s expectations. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs 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 qualify as breakthrough therapies, the ~~91FDA~~ -- **FDA** may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may seek Fast Track Designation by the FDA for a product candidate that we develop, and we may be unsuccessful. If we are successful, the designation may not actually lead to a faster development or regulatory review or approval process. We may seek Fast Track Designation for the product candidates we develop. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, as we have for ~~HB~~ **eseba** - ~~200~~ **vec** in combination with pembrolizumab, for the treatment of first- line advanced / metastatic HPV16 HNSCC, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track

Designation if it believes that the designation is no longer supported by data from our clinical development program. We may seek Orphan Drug Designation for product candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity. As part of our business strategy, we may seek Orphan Drug Designation for any product candidates we develop, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. Similarly, in Europe, the European Commission may grant orphan designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan designation application. Orphan designation is intended to promote the development of drugs that are intended (i) for the diagnosis, prevention or treatment of life- threatening or chronically debilitating conditions, (ii) either the conditions affect no more than 5 in 10, 000 persons in the EU or without the benefits derived from orphan status, it is unlikely that sales of the product in the EU would be sufficient to justify the necessary investment in developing the product, and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition. In the EU, orphan designation entitles a party to a number of incentives, such as protocol assistance, access to the centralized marketing authorization procedure, and potential fee reductions or waivers depending on the status of the sponsor. Generally, if a drug with an orphan designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. Similarly, the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication. The applicable period is seven years in the United States and ten years in the EU. The EU exclusivity period can be reduced to six years if, at the end of the fifth year, a drug no longer meets the criteria on the basis of which ~~it~~ **86it** received orphan designation, including where it can be demonstrated on the basis of available evidence that the drug is sufficiently profitable such that market exclusivity is no longer justified or where the prevalence of the condition has increased above the threshold. ~~92Even~~ -- **Even** if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off- label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Similar considerations apply abroad. While we may seek Orphan Drug Designation for applicable indications for our current and any future product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations. Our business operations and current and future relationships with investigators, health care professionals, consultants, third- party payors and customers will be subject, directly or indirectly, to federal, state and foreign healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Although we do not currently have any products on the market, if we obtain FDA approval for our product candidates, and begin commercializing those products in the United States, our operations may be directly, or indirectly through our prescribers, customers and third- party payors, subject to various U. S. federal and state healthcare laws and regulations, including, without limitation, the U. S. federal Anti- Kickback Statute, the U. S. federal civil and criminal false claims laws, ~~federal~~ **the** ~~health~~ **Health** ~~data privacy laws~~ **Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively " HIPAA ")** , and the Physician Payments Sunshine Act and regulations. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U. S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by comparable foreign regulatory authorities in jurisdictions in which we conduct our business that may affect our ability to operate. See " Business – Other U. S. Healthcare Laws. " The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as

responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company' s attention from the business. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental and regulatory authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may ~~apply~~ **87apply** to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U. S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws and the delay, reduction, ~~93termination~~ -- **termination** or curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time- consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected. Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti- bribery laws of European countries, national sunshine rules, regulations, industry self- regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is not permitted in the countries that form part of the European Union. Some European Union Member States, and the United Kingdom, through the United Kingdom Bribery Act 2010, have enacted laws explicitly prohibiting the provision of these types of benefits and advantages. Infringements of these laws can result in substantial fines and imprisonment. Payments made to physicians in certain European Union Member States (e. g., France or Belgium) must be publicly disclosed. Moreover, agreements with physicians may be the subject of prior notification and approval by the physician' s employer, his or her competent professional organization and / or the regulatory authorities of the individual European Union Member States. These requirements are provided in the European Union Member State national laws, industry codes (e. g. the European Federation of Pharmaceutical Industries and Associations Disclosure and Healthcare Professionals Codes) or professional codes of conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of a product candidate in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval for that product candidate in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, in order to market and sell our drugs in the European Union and many other jurisdictions, we, and any collaborators we may have in the future, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the drug be approved for reimbursement before the drug can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to regulatory approval. We, and any collaborators we may have in the future, may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all. European data collection and processing is governed by restrictive regulations governing the use, processing and cross- border transfer of personal information. The collection, use, storage, disclosure, transfer or other processing of personal data, including personal health data regarding individuals in the EEA is governed by the EU GDPR. The EU GDPR is wide ranging in scope and imposes several requirements on companies that process personal data, including requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data ~~processing~~ **88processing** obligations to the competent national data protection authorities and the security and confidentiality of the personal data. Failure to comply with the requirements of the EU GDPR and the related national data protection laws of the EU Member States may result in fines and other administrative penalties, including potential fines of up to € 20 million or 4 % of annual global revenues, whichever is greater, for breach or non- compliance. ~~94In~~ **In** addition, further to the UK' s exit from the EU on January 31, 2020, the EU GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK' s European Union (Withdrawal) Act 2018 incorporated the EU GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK' s data protection regime, which is independent from but aligned to the EU' s data protection regime. Non- compliance with the UK GDPR may result in monetary penalties of up to £ 17. 5 million or 4 % of worldwide revenue, whichever is higher. Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR. The UK government has announced plans to reform the data protection legal framework in the UK in its Data ~~Protection~~ **(Use** and ~~Digital Information~~ **Access)** Bill. The potential misalignment between future UK laws and regulations and EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of EU / UK personal information and our privacy and data

security compliance programs and could require us to implement different compliance measures for the UK and the EU. The EU GDPR also imposes strict rules on the transfer of personal data out of the EEA, including to the United States. Although the UK is regarded as a third country under the EU GDPR, the EC has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with EU and UK data protection laws. There are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EU' s Standard Contractual Clauses, the UK' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK Extension thereto (which allows for transfers for relevant U. S.- based organizations who self- certify compliance and participate in the Framework). However, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. The EU GDPR and UK GDPR also confer a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the EU GDPR and UK GDPR. The EU GDPR and UK GDPR regulations may impose additional responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with these and / or new data protection rules. This may be onerous and adversely affect our business, financial condition, prospects and results of operations. Compliance with the EU GDPR and UK GDPR will be a rigorous and time- intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Our business activities may be subject to the Foreign Corrupt Practices Act and similar anti- bribery and anti- corruption laws. Our business activities may be subject to the FCPA and similar anti- bribery or anti- corruption laws, regulations or rules of other countries in which we operate, including the U. K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non- U. S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. The anti- bribery provisions of the FCPA are enforced primarily by the Department of Justice (**“** DOJ **”**) and the Securities and Exchange Commission ~~, (SEC)~~ is involved with enforcement of the books and records provisions of the FCPA and may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. Recently the SEC and DOJ have increased their ~~FCPA~~ **89FCPA** enforcement activities with respect to pharmaceutical companies. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non- U. S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. ~~95There~~ -- **There** is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition. Our ability to utilize our foreign net operating loss carryforwards may be limited by GILTI taxation introduced through the tax reform. We have incurred substantial losses during our operating history. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. The tax reform legislation introduced section 951A, a new tax on so- called “ global intangible low- taxed income, ” or GILTI. GILTI applies to income of a controlled foreign corporation (CFC) that is not otherwise subpart F income. Our Austrian subsidiary is expected to be treated as a CFC and GILTI taxation may therefore apply when use of foreign net operating loss carryforwards reduce our foreign income tax to a low level. Tax benefits from the use of our foreign net operating loss carryforwards could be partially offset by U. S. GILTI taxation, which could have an adverse effect on our future results of operations. Changes to section 174 capitalization rules through the tax reform may impact our ability to immediately deduct research and development expenses, leading to higher taxable income and effective income tax payments even before reaching profitabilityThe tax reform legislation also altered section 174, by requiring that, beginning with the year 2022, research and development expenses be capitalized and amortized over five years for expenditures incurred in the U. S. and 15 years for expenditures incurred outside the U. S. Therefore, our ability to use research and development expenses to offset revenue in the coming years, may be limited, and we may be required to record taxable income while our business is actually still loss- making. The resulting tax payments could have an adverse effect on our future results of operations. Risks Related to Our Intellectual PropertyOur rights to develop and commercialize our product candidates are subject, in part, to the terms and conditions of licenses granted to us by others, and, if we fail to comply with our obligations under these arrangements or resolve related disputes, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property. We are dependent on patents, know- how and proprietary technology, both our own and licensed from others. We license patents related to our non- replicating and replicating technologies and certain other intellectual property rights from third parties, including from the University of Geneva, the University of Basel, the University of Zurich and the University of

Minnesota and expect in the future to be party to other material license or collaboration agreements. These agreements typically impose numerous obligations, such as diligence and payment obligations, including in relation to revenues we may receive from any sublicenses we grant in respect of the licensed patents. If we fail to comply with our obligations under these agreements, our licensors may have the right to terminate our licenses, in which event we might not be able to develop, manufacture or market any product that is covered by the intellectual property we in- license from such licensor and may face other adverse consequences. These licenses do and future licenses may also ~~include~~ **90include** provisions that impose obligations and restrictions on us that could delay or otherwise negatively impact a transaction that we may wish to enter into. ~~96Disputes~~ **Disputes** may also arise between us and our licensors regarding the license agreements we have with them, including with respect to: ● the proper interpretation of the license agreement terms, including with respect to our right to sublicense patent rights and any other intellectual property rights to third parties and the amount of fees owed to the licensors as a result of such sublicenses; ● our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and ● the ownership of inventions and know- how created by us and our partners using a combination of our own intellectual property and that licensed from our licensors. If disputes arise that prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer. If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market. We rely upon a combination of patents, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies. Such means may afford only limited protection of our intellectual property and may not: (i) prevent our competitors from duplicating our technology or product candidates; (ii) prevent our competitors from gaining access to our proprietary technology; or (iii) permit us to gain or maintain a competitive advantage. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by the third parties to which we grant access to such intellectual property, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. These third parties also may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property- related proceedings that could jeopardize or invalidate our proprietary information and intellectual property. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Our success depends in large part on our ability to obtain and maintain patent protection with respect to our non- replicating technology, our replicating technology, including our ~~HB~~ **eseba** - ~~200~~ **vec** and HB- 700 product candidates, the vaccine product candidates we are developing with Gilead for HBV (HB- 400) and HIV (HB- 500), and other proprietary product candidates. Although we own or license from others certain patents and patent applications that cover some of the foregoing technologies and product candidates, we do not currently own or license from others issued patents covering all of the foregoing technologies and product candidates. Our reliance on patent applications carries certain risks associated with pending patent applications prior to the issuance of patents, as described below. If we do not adequately obtain and protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our product candidates that are important to our business. The patent application and approval process is expensive and time- consuming and we may not ~~be~~ **91be** able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We cannot predict: ● if and when patents will issue from our patent applications; ~~97~~ ● the degree and range of protection any patents that we obtain will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents; ● whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or ● whether we will need to initiate litigation or administrative proceedings related to obtaining, protecting or enforcing our patents, which may be costly whether we win or lose. We cannot be certain that the claims in our pending patent applications covering composition of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered patentable by courts in the United States or foreign countries. Certain of our issued patents and pending applications are method of use patents, which protect the use of a product for a specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products " off- label. " Although off- label prescriptions may induce or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights may be uncertain. The patent applications that we own or in- license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if patents do successfully issue from such applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. If our patents are rendered invalid or unenforceable, or narrowed in scope, the patent coverage afforded our products could be impaired. Such impairment could significantly impede our ability to market our products, negatively affect our competitive position and harm our business and operating results. In addition, 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.

In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our patent protection. No assurances can be given that third parties will not create new products or methods that achieve similar results without infringing upon patents we own. If these developments were to occur, it could have an adverse effect on our sales or market position. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. If we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects. ~~Given~~ **92Given** 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. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the ~~98Hatch~~ **Hatch** - Waxman Amendments, and similar legislation in the European Union. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and 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. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for U. S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. It is also possible for third parties to file observations with various patent offices during the patent application process. Various post grant review proceedings, such as inter partes review and post grant review in the United States and opposition proceedings at the EPO, are available for any interested third party to challenge the patentability of claims issued in patents to us. Some of these procedures are relatively new and can be unpredictable. For example, the EP' 504 Patent, which is owned by the University of Geneva and is exclusively licensed to us, was opposed by a third- party at the EPO. The Opposition Division of the EPO eventually dismissed the opposition and maintained the patent as granted. In addition to the protection afforded by patents, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know- how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know- how, information, or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know- how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition. Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, inter partes review and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As ~~the~~ **93the** biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and certain other development activities in the United States is not considered an act of

infringement. If and when any of our product candidates are approved by the FDA, a third party may then seek to ~~99enforce~~ **enforce** its patent by filing a patent infringement lawsuit against us. While we are aware of certain third- party patents and applications that relate to similar subject matter as our technologies, we do not believe that any patent claims that could otherwise materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable. We may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is " clear and convincing, " a heightened standard of proof. There may be third- party patents of which we are currently unaware which cover materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, **which may not be available on commercially reasonable terms, if at all,** or until such patents expire or they are determined to be held invalid or unenforceable. Similarly, if any third- party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license, which may not be available on commercially reasonable terms, if at all, or until such patent expires or is determined to be invalid or unenforceable. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in- licenses. Presently we have rights to certain intellectual property, through licenses from third parties and under patents and / or patent applications that we own or will own, related to ~~HB~~ **eseba** - ~~200~~ **vec** , HB- 700, HB- 400, HB- 500 and certain other product candidates. Because additional product candidates may require the use of proprietary rights held by third parties, such as the rights to use certain antigens that are, specific to future disease targets, the growth of our business will likely depend in part on our ability to acquire, in- license or use these proprietary rights. In addition, while we have patent rights directed to certain non-replicating and replicating technologies **,** we may not be able to obtain intellectual property to all uses of non- replicating and replicating technologies. Our product candidates may also require specific formulations to work effectively and efficiently and rights to such formulations may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these ~~compositions~~ **94compositions** or methods may be owned by third parties. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify. Even if we are able to obtain a license to use such intellectual property, it may be non- exclusive, which would not restrict the licensor party from giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the specific antigens that will be used with our product candidates may be covered by the intellectual property rights of others. ~~100The~~ **The** licensing and acquisition of third- party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing

products, which may be impossible or require substantial time and monetary expenditure. For certain of our in- licensed patent rights, such as patent rights in- licensed from the University of Geneva, the University of Basel and the University of Zurich, we may not have the right to file a lawsuit for infringement and may have to rely on a licensor to enforce these rights for us. If we are not able to directly assert our licensed patent rights against infringers or if a licensor does not vigorously prosecute any infringement claims on our behalf, we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result. Post- grant proceedings, including interference proceedings, provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patents or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not agree to a license on commercially reasonable terms or at all. Litigation or post- grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. ~~Obtaining~~ **95Obtaining** and maintaining our 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 fees, renewal fees, annuity fees and various other government fees on patents and / or patent applications **are** ~~will be~~ due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of our patents and / or patent applications and any patent rights we may obtain in the future. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. 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 ~~101noncompliance~~ --- **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. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO. If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that such patent is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, inter partes review, post grant review, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidate. Such a loss of patent protection could have a material adverse impact on our business. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology or pharmaceutical industry involve both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. In addition, the United States continues to adapt to wide- ranging patent reform legislation that became effective starting in 2012. Moreover, recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent scope is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce our patent rights. For example, the Biden administration ~~recently~~ indicated its support for a proposal at the World Trade Organization to waive patent rights with respect to COVID- 19 vaccines. Any waiver of our patent or other intellectual property ~~protection~~ **96protection** by the U. S. and other foreign governments could have a material adverse effect on our competitive position, business, financial condition and results of operations. For example, recent decisions raise questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have been issued without PTA. Thus, it cannot be

said with certainty how PTA will or will not be viewed in the future and whether patent expiration dates may be impacted. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but ~~,~~ the complexity and uncertainty of European patent laws has also increased in recent years. For example, in Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, ~~102increasing ---~~ **increasing** the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. 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. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business. We have less robust intellectual property rights in certain foreign jurisdictions and may not be able to protect our intellectual property rights throughout the world. Certain of our key patent families have been filed in the United States, as well as in numerous jurisdictions outside the United States. However, our intellectual property rights in certain jurisdictions outside the United States may be less robust. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in certain 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 may export otherwise infringing products to territories where we have patent protection. 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. A portion of our patent portfolio is **still** at **an** ~~the very~~ early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines. 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 biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent 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 and 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 rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by an employee, consultant, or contractor, as applicable, in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. We may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ~~ability~~ **97ability** to capture the commercial value of such intellectual property. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. We may be subject to claims that former collaborators or other third parties have an ownership interest in our patents or other intellectual property, including our in- licensed patent rights. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time-consuming. If we are unsuccessful, we could lose valuable rights in intellectual property that we regard as our own. ~~103We~~ **We** may be subject to claims that our employees, consultants or contractors have wrongfully used or disclosed confidential information of third parties. We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees from their normal responsibilities. If we are not successful, in addition to paying monetary damages, we could lose access or exclusive access to valuable intellectual property and personnel. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights. The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technologies, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative: ● pending patent applications that we own or license may not lead to issued patents; ● patents, should they issue, that we own or license, may not

provide us with any competitive advantages, or may be challenged and held invalid or unenforceable; ● others may be able to develop and / or practice technology that is similar to our technology or aspects of our technology but that is not covered by our owned or in- licensed patents, should any such patents issue; ● third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection; ● we, or our licensors, might not have been the first to make the inventions covered by a pending patent application that we own or license; ● we, or our licensors, might not have been the first to file patent applications covering a particular invention; ● others may independently develop similar or alternative technologies without infringing our intellectual property rights; ● we may not be able to obtain and / or maintain necessary licenses on reasonable terms or at all; ● third parties may assert an ownership interest in our intellectual property, including our in- licensed patent rights, and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property; ● we may not be able to maintain the confidentiality of our trade secrets or other proprietary information; **98** ● we may not develop or in- license additional proprietary technologies that are patentable; and ● the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business and results of operation. ~~104Risks~~ --- **Risks** Related to Employee Matters, Managing Our Growth and Other RisksThe contractual obligations of Daniel Pinschewer to the University of Basel may present conflicts of interest. Daniel Pinschewer, M. D., Founder and Chief Scientific Officer until March 2020, who ~~serves~~ **served** as our Scientific Advisor to the Chief Executive Officer **until December 2024** , ~~provides~~ **provided** research services to us pursuant to a consulting agreement. Dr. Pinschewer is also an employee of the University of Basel where he engages in, among other activities, academic research related to arenaviruses and our technology platform. Pursuant to a separate research service agreement with the University of Basel, the university provides us with on- going services with respect to our technologies, and employs the services of Dr. Pinschewer to perform some of these services. As an employee of the University of Basel, Dr. Pinschewer is subject to the university' s rules of conduct, such as confidentiality, academic objectivity and transparency of research with respect to his academic research. As a result of Dr. Pinschewer' s obligations to the University of Basel and his ~~current~~ **previous** role as our Scientific Advisor to the Chief Executive Officer, circumstances may arise that could create or appear to create conflicts of interest when, we, the University of Basel or Dr. Pinschewer are faced with decisions that could have different implications for the University of Basel and our company. Additionally, we would not automatically obtain rights to inventions that are developed by Dr. Pinschewer unless the inventions were made in the course of his consulting services to us. Furthermore, other research being conducted by the University of Basel may receive higher priority than research and services related to our technology platform. Any potential disagreement or dispute that may arise with the University of Basel relating to the ownership of Dr. Pinschewer' s inventions, conflicts of interest or otherwise may result in a delay or termination of the research, development or commercialization of our product candidates or may have other negative consequences for our company. We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. We are highly dependent on members of our executive team ~~, including our Chief Executive Officer, Joern Aldag~~ . Although we have formal employment agreements with our executive officers, any of our executive officers could leave our employment at any time, or within a contractual termination period that is too short to find an adequate replacement. We currently do not have " key person " insurance on any of our employees. The loss of the services of our executive officers or other key employees may adversely impact the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. **Any significant leadership change or senior management transition involves risk, especially nearly simultaneous changes involving senior level leadership positions. For example, on July 22, 2024, Joern Aldag separated as our Chief Executive Officer and Reinhard Kandera separated as our Chief Financial Officer. In addition, on July 22, 2024, Dr. Malte Peters was appointed as our Chief Executive Officer and Terry Coelho was appointed as our Executive Vice President and Chief Financial Officer. Any failure to effectively transition these senior executive leadership changes or to retain Dr. Peters or Ms. Coelho on our executive team could hinder our strategic planning, business execution and future performance.** Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. We primarily conduct our operations at our facility in Vienna, Austria. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous biotechnology and pharmaceutical companies and academic institutions for skilled individuals. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. To induce valuable employees to join and remain at our company, in addition to salary and cash incentives, we have provided, and intend to continue to provide, stock options that vest over time. The value of these equity grants that ~~vest~~ **99vest** over time to our employees may be significantly affected by movements in the fair market value of our capital stock that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Moreover, many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Accordingly, our future success depends on our ability to continue to attract and retain current and additional executive officers and other key employees. The inability to recruit, or the loss of services of certain executives, key ~~105employees~~ --- **employees** , consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and prospects. Our strategic refocus and the associated workforce reduction announced in January **2024 and additional workforce reductions implemented in September 2024 and November** 2024 may not result in anticipated cost savings, could result in total costs and expenses that are greater than expected and could disrupt our business. In January

2024, we announced a reduction in workforce by approximately 30 % in connection with the strategic refocus of our business to prioritize and focus on our lead assets. **The reduction in force was a component of our broader efforts to prioritize the clinical development of our eseba- vec program for the treatment of HPV16 head and neck cancers and our two Gilead-partnered infectious disease programs, and to pause development activities related to HB- 300 and most of our preclinical research activities. In September 2024, in connection with this strategic refocus, we implemented an enterprise- wide initiative intended to improve our business through specialized organizational programs that include targeted cost- savings, including a further reduction in workforce by approximately 20 %. Going forward, we may implement further cost- saving initiatives that could result in additional restructuring charges including severance and other employee charges. In November 2024, we approved a plan to continue to improve our cost structure and operating efficiency, including a further reduction in workforce by approximately 80 % of our then- current employee base. In connection with the additional restructuring, in an effort to rebalance our cost structure in alignment with our strategic refocus and development of our oncology portfolio, we also announced that we would pause clinical development in our eseba- vec program for the treatment of HPV16 head and neck cancers, including an early termination of our Phase 1 / 2 clinical trial for the treatment of HPV16 cancers. While we will continue to seek partnering opportunities for the eseba-vec program, we will focus primarily on progressing the Phase 1- ready HB- 700 program for the treatment of KRAS mutant cancers.** We may not realize, in full or in part, the anticipated benefits, savings and improvements in our operating structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our results of operation and financial condition would be adversely affected. **Furthermore,** ~~We expect to incur additional costs as we recognize one- time employee termination- related charges. We also cannot guarantee that we will not have to undertake additional workforce reductions or~~ **our strategic** restructuring ~~activities in the future. Furthermore, our strategic Restructuring Plan~~ **plan** may be disruptive to our operations. For example, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day- to- day operations and reduced employee morale. If employees who were not affected by the reduction in force seek alternate employment, this could result in us seeking contract support which may result in unplanned additional expense or harm our productivity. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, and clinical personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing our product candidates in the future. We may need to grow or contract our organization, and we may experience difficulties in managing this growth or contraction, which could disrupt our operations. In addition to the risks associated with a reduction in force, as our finances, development and commercialization plans and strategies evolve, we may choose to expand or contract our employee base for managerial, operational, manufacturing, financial and other resources. Future growth or additional contraction would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day- to- day activities and devote a substantial amount of time to managing either growth or ~~contraction~~ **100contraction** activities. We may not be able to effectively manage our operations which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage such growth, our expenses may increase more than expected, our ability to generate and / or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively with others in our industry will depend, in part, on our ability to effectively manage any such growth. We will need to grow the size of our organization, and we may experience difficulties in managing this growth. Although we recently implemented **a series of** ~~an approximately 30 % reduction in our~~ workforce **reductions** and discontinued our GMP manufacturing facility project as part of our recent strategic refocus, as our research, development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including: ● identifying, recruiting, integrating, maintaining and motivating additional employees; ~~106~~ ● managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and ● improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. Due to our limited financial resources and the limited experience of some members of our management team in managing a public company, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may also lead to significant costs. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical trial management and manufacturing. Our independent organizations, advisors and consultants may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities. There can be no assurance that the services of independent organizations,

advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. ~~Risks~~ **101Risks** Related to Ownership of Our Common StockAn active trading market for our common stock may not be sustainable, and you may not be able to resell your shares of our common stock at or above the purchase price. An active trading market for our shares may not be sustained. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. As a result of these and other factors, it may be difficult for our stockholders to resell their shares of our common stock at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration ~~. Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock. If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market, such as the minimum closing bid price requirement, The Nasdaq Stock Market, LLC (Nasdaq) may take steps to delist our common stock. Under Nasdaq rules, the closing bid price for our common stock must remain at or above $ 1. 00 per share to comply with Nasdaq' s minimum bid requirement for continued listing. On August 3, 2023, we received a letter from the Listing Qualifications Department of Nasdaq notifying us that, for the last 30 consecutive business days, the closing bid price for our common stock has been below the minimum $ 1. 00 per share required for continued listing on The Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450 (a) (1) (the Minimum Bid Price Requirement). Under Nasdaq Listing Rule 5810 (c) (3) (A), we have been granted a 180 calendar day grace period, or until January 30, 2024, to regain compliance with the Minimum Bid Price 107Requirement. The Minimum Bid Price Requirement will be met if our common stock has a minimum closing bid price of at least $ 1. 00 per share for a minimum of ten consecutive business days during the 180 calendar day grace period. However, we failed to regain compliance prior to January 30, 2024. Accordingly, on January 18, 2024, we applied for and on January 31, 2024 were granted by the Listing Qualifications Department of Nasdaq the right to list our common stock on the Capital Market and to have an additional 180 calendar days, or until June 29, 2024, to regain compliance with the Minimum Bid Price Requirement. We are monitoring the closing bid price of our common stock; however, there can be no assurance that we will be able to regain compliance with the Minimum Bid Price Requirement. The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from Nasdaq, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities. Moreover, there is no assurance that any actions that we take to restore our compliance with the Minimum Bid Price Requirement would stabilize the market price or improve the liquidity of our common stock, prevent our common stock from falling below the minimum bid price required for continued listing again or prevent future non- compliance with Nasdaq' s listing requirements~~ . The price of our stock may be volatile. The trading price of our common stock could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The market price for our common stock may be influenced by many factors, including: ● the commencement, enrollment or results of the clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates; ● any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including without limitation the FDA' s issuance of a " refusal to file " letter or a request for additional information; ● adverse results or delays in clinical trials; ● our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial; ● adverse regulatory decisions, including failure to receive regulatory approval of our product candidates; ● changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals; ● adverse developments concerning our manufacturers; ● our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices; ● our inability to establish collaborations if needed; ● our failure to commercialize our product candidates; ● additions or departures of key scientific or management personnel; ● unanticipated serious safety concerns related to the use of our product candidates; ~~108~~ ● introduction of new products or services offered by us or our competitors; ● announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; ● our ability to effectively manage our growth or concentration; **102** ● the size and growth of our initial cancer target markets; ● our ability to successfully treat additional types of cancers or at different stages; ● actual or anticipated variations in quarterly operating results; ● our cash position; ● our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; ● publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts; ● changes in the market valuations of similar companies; ● overall performance of the equity markets; ● sales of our common stock by us or our stockholders in the future; ● trading volume of our common stock; ● changes in accounting practices; ● ineffectiveness of our internal controls; ● disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; ● significant lawsuits, including patent or stockholder litigation; ● general political and economic conditions; and ● other events or factors, many of which are beyond our control. In addition, the stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our

common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources, which would harm our business, operating results or financial condition. ~~109Our~~ **Our** principal stockholders and management own a significant percentage of our stock and exert significant influence over matters subject to stockholder approval ~~. Our Class A common stock has no voting rights. As a result, all matters submitted to our stockholders are decided by the vote of holders of our common stock~~ . Our executive officers, directors, and 5 % stockholders beneficially own approximately 40 % of our outstanding voting stock. These stockholders may be able to determine many matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock. ~~Our~~ **103Our** operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance. Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and / or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and, if approved, sales of our product candidates. These upfront and milestone payments may vary significantly from period to period and any variance could cause a significant fluctuation in our operating results from one period to the next. Further, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following: ● the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time; ● the timing and outcomes of clinical trials for our current and any other future product candidates; ● the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers; ● our ability to adequately support our future growth; ● potential unforeseen business disruptions that increase our costs or expenses; ● future accounting pronouncements or changes in our accounting policies; and ● the changing and volatile global economic environment. The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. The price of our common stock could decline even when we have met any previously publicly stated revenue and / or earnings guidance we may provide. ~~110We~~ **We** expect to continue to incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives. As a public company, and particularly ~~after~~ **now that** we are no longer an emerging growth company, as defined in the JOBS Act, we ~~will~~ incur significant legal, accounting and other expenses that we did not incur as a private company. Our status as an " emerging growth company " ~~will end~~ **ended** on December 31, 2024 ~~, at the latest~~ . The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq 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. We expect that we will continue to need to hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being, a public company and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will continue to increase our legal and ~~financial~~ **104financial** compliance costs and will make some activities more time- consuming and costly. We are continuously evaluating these rules and regulations which are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Pursuant to Section 404 of the Sarbanes- Oxley Act (SOX Section 404) we are required to furnish a report by our management on our internal control over financial reporting with our Annual Report on Form 10- K with the SEC ~~. However, while we remain an~~ **and** ~~emerging growth 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. **However** ~~After no longer qualifying as an emerging growth company~~ , we may, under certain conditions, still qualify as a " smaller reporting company " and benefit from similar exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. To achieve compliance with SOX Section 404 within the prescribed period, we ~~will be engaged~~ **engage** 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 SOX Section 404. If

we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur. Anti- takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include: ● a board of directors divided into three classes serving staggered three- year terms, such that not all members of the board will be elected at one time; ~~111~~ ● a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders; ● a requirement that special meetings of stockholders be called only by our board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office; ● advance notice requirements for stockholder proposals and nominations for election to our board of directors; ● a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two- thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors; **105** ● a requirement of approval of (i) not less than two- thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action and (ii) the majority of the outstanding shares of our voting stock to amend specific provisions of our certificate of incorporation; and ● the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15 % or more of our outstanding voting stock. These anti- takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline. Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers and employees to us or our stockholders, (iii) any action asserting a claim against us or any of our current or former directors, officers, or other employees or stockholders arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws, or (v) any action asserting a claim against us or any of our current or former directors or officers or other employees that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the jurisdiction. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision of our amended and restated certificate of incorporation or amended and restated bylaws inapplicable to, or unenforceable in respect of, one ~~112or~~ **or** more of the specified types of actions or proceedings, we may incur additional costs, which could have a material adverse effect on our business, financial condition or results of operation. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. Upon the closing of our initial public offering in April 2019, we became subject to the periodic reporting requirements of the Exchange Act. We are continuing to refine our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. ~~These~~ **106These** inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. Pursuant to Section 404 of Sarbanes- Oxley, our

management is required to report upon the effectiveness of our internal control over financial reporting. **In addition,** ~~When we lose our status as an " emerging growth company " and~~ if we do not qualify as a " smaller reporting company " at ~~such~~ **the** time **we file an Annual Report on Form 10- K** , our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. General RisksAdverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions or transactional counterparties, could adversely affect the Company' s current and projected business operations and its financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, such as the failure of Silicon Valley Bank and various regional banks in 2023, have in the past and may in the future lead to market- wide liquidity problems. If any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, if any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a ~~113financial~~ --- **financial** institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. Heightened inflation and increases in interest rates may increase our labor costs, costs to conduct clinical trials and other operational costs, or adversely affect our ability to obtain additional funding on attractive terms. Although inflation has not had a material impact on our business or operating results historically, inflation, has had, and may continue to have, an impact on the labor costs we incur to attract and retain qualified personnel, costs to conduct clinical trials and other operational costs. Inflationary costs could adversely affect our business, financial condition and results of operations. Increased interest rates may adversely affect our borrowing rate and our ability to obtain, or the terms under which we can obtain, any potential additional funding. ~~Our~~ **107Our** employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the regulations of the FDA and other comparable foreign regulatory bodies, provide true, complete and accurate information to the FDA and other comparable foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements generally. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee and other third- party misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting 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 civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations. Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the use of potentially hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We could incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our

operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third- party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or ~~114injury~~ --- **injury** resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of changes to applicable laws and regulations and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Although we maintain 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. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. ~~We~~ **108We** are subject to stringent and evolving U. S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences. In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third- party data, business plans, transactions, clinical trial data and financial information (collectively, sensitive data). Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws). For example, ~~the federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), as amended by the Health Information Technology for Economic and Clinical Health Act (" HITECH "),~~ imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. For more information regarding risks associated with HIPAA, please refer to the section above that discusses risks associated with U. S. healthcare laws. In the past few years, numerous U. S. states ~~— including California, Virginia, Colorado, Connecticut, and Utah —~~ have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (" CPRA ") (collectively, " CCPA "), applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $ 7, 500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws may impact (possibly significantly) our business activities depending on how it is interpreted, should we become subject to the CCPA in the future. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties ~~upon~~ **with** whom we ~~rely~~ **work** . ~~115Outside~~ --- **Outside** the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, EU GDPR and the UK GDPR impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR or, in each case, 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. We may be subject to new laws governing the privacy of consumer health data, including reproductive, sexual orientation, and gender identity privacy rights. For example, Washington' s My Health My Data Act (" MHMD ") broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws. ~~Our~~ **109Our** employees and personnel use generative artificial intelligence (" AI ") technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross- border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA)

and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt **or have already adopted** similarly stringent ~~interpretations of their~~ data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA' s standard contractual clauses, the UK' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some EU regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the EU GDPR' s cross- border data transfer limitations. In addition to data privacy and security laws, we are bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We also publish privacy policies, marketing materials, **whitepapers** and other statements ~~regarding~~ **concerning** data privacy and security **, Regulators in the United States are increasingly scrutinizing these statements,** and if these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, **misleading** or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences. Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties **with whom we work** ~~that process personal data on our behalf~~. ~~116We~~ **We** may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties ~~on~~ **with** whom we ~~rely~~ **work** may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties ~~on which~~ **with whom** we ~~rely~~ **work** fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- action claims) and mass arbitration demands; additional reporting requirements and / or oversight; bans on processing personal data (including clinical trial data); and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our ~~products~~ **110products** ; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operationsCybersecurity risks and the failure to maintain the security, confidentiality, integrity, and availability of our information technology systems or data, and those maintained on our behalf, could result in adverse consequences that materially affect our business, including without limitation regulatory investigations or actions, a material disruption of the development programs of our product candidates, damage to our reputation and / or subject us to costs, loss of customers or sales, fines and penalties or lawsuits. In the ordinary course of our business, we collect and store sensitive data, and, as a result, we and the third parties ~~upon which~~ **with whom** we ~~rely~~ **work** face a variety of evolving threats that could cause security incidents. We manage and maintain our applications and data utilizing on- site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information, including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks or other services to us pose increasing risks. Cyber- attacks, malicious internet- based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties ~~upon which~~ **with whom** we ~~rely~~ **work** . Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties ~~upon which~~ **with whom** we ~~rely~~ **work** may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services. We and the third parties ~~upon which~~ **with whom** we ~~rely~~ **work** are subject to a variety of evolving threats, including but not limited to computer hacking, phishing attacks and social engineering (including through deep fakes, which may be increasingly more

difficult to identify as fake), supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, ransomware, dissemination of malware, computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, credential stuffing, credential harvesting, personnel misconduct or error as well as power outages, telecommunications failures, natural disasters (including extreme weather), terrorist attacks or other similar events. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. If such events were to occur and cause interruptions in ~~117our~~ **our** operations, it could result in a material disruption of our development programs and our business operations, such as the loss of clinical trial data from completed or future clinical trials. Such loss could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events. ~~For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data.~~ Remote work ~~has become more common and~~ has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. We may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. ~~We~~ **111We** rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation the manufacture of our product candidates and to conduct clinical trials. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences, including the unauthorized access, disclosure and use of sensitive data, including information from our patient registry or other patient information, which is protected by HIPAA, and other laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, damage to our reputation and the further development and commercialization of our product candidates could be delayed. In addition, our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of our suppliers are affected by a man- made or natural disaster or other business interruption. Damage or extended periods of interruption to our third- party collaborators', including Gilead' s, corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause them to cease or delay development. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud- based information systems, the related security risks will increase **,** and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third- party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyber- attack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We also take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and / or software, including that of third parties ~~upon which~~ **with whom** we ~~rely~~ **work**). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. **Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past and we expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our products and services.** We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry- standard or reasonable security measures to protect our information technology systems and sensitive data. Applicable data privacy and security obligations may require us **, or we may voluntarily choose,** to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents **, or to take other actions, such as providing credit monitoring and identity theft services** . Such disclosures ~~are~~ **and related actions can be** costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. ~~118~~ **If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing**

sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant 112