

Risk Factors Comparison 2025-03-05 to 2024-03-06 Form: 10-K

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The following risk factors and other information included in this Annual Report on Form 10- K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see the Section titled “ Forward- Looking Statements ” in this Annual Report on Form 10- K for a discussion of some of the forward- looking statements that are qualified by these risk factors. These factors could materially and adversely affect our business, financial condition, results of operations and future growth prospects. Risks related to the development of our product candidates We must complete successful preclinical studies and clinical trials that demonstrate the safety and efficacy of our product candidates before we can begin the commercialization process. We are focused on the development of belrestotug, ~~inupadenant, and EOS-984~~, and EOS- 215. A key part of our strategy, however, is to continue to pursue clinical development of additional product candidates designed to address the main causes of PD- 1 or other standard- of- care resistance. Developing, obtaining marketing approval for, and commercializing product candidates requires substantial funding and remains subject to the risks of failure inherent at each stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. The results of preclinical studies, preliminary study results, and early clinical trials of our current product candidates and any future product candidates may not be predictive of the results of later- stage clinical trials. Even if early- stage clinical trials are successful, we may need to conduct additional clinical trials of our product candidates in additional patient populations or under different treatment conditions before we are able to seek approvals from the FDA or comparable foreign regulatory authorities. Our product candidates may not perform as we expect, may ultimately have a different or no impact on tumors, may have a different mechanism of action than we expect, and may not ultimately prove to be safe and effective. We may modify development plans, including selecting different combinations or indications or discontinuing clinical activities, or determine to pursue development of different product candidates as we obtain additional clinical and nonclinical data. Results from preclinical studies and early- stage trials, and trials in compounds that we believe are similar to ours, may not be representative of results that are found in larger, controlled, blinded, and longer- term studies and trials. Product candidates may fail at any stage of preclinical or clinical development. Product candidates may fail to show the desired safety and efficacy traits even if they have progressed through preclinical studies or initial clinical trials. Preclinical studies and clinical trials may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, notwithstanding promising results in earlier preclinical studies or clinical trials or promising mechanisms of action. In some instances, 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. Moreover, flaws in the design of a clinical trial can negatively impact results. We may not discover such a flaw prior to advance stages of a clinical trial. Additionally, our clinical trials ~~to date~~ (except for the recently initiated GALAXIES- 301 trial) have been open- label trials, where both the patient and investigator know whether the patient is receiving the investigational product candidate or an existing approved drug, which may introduce study bias. Most typically, open- label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when they are receiving treatment. In addition, open- label clinical trials may be subject to an “ investigator bias ” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Positive results observed in open- label trials may not be replicated in later placebo- controlled trials. We may also experience events during, or as a result of, clinical trials that could delay and could prevent our ability to receive marketing approval or commercialize our product candidates, including: • regulators or IRBs /RECs may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or may require that we modify or amend our clinical trial protocols; • we may experience delays in reaching, or fail to reach, agreement on acceptable terms for clinical trial contracts or clinical trial protocols with prospective trial sites and / or clinical research organizations ~~or (“ CROs ”)~~; • clinical trials may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; • the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials often is slow, participants may drop out of these clinical trials or be lost to follow- up at a higher rate than we anticipate, or participants may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our product candidates; • our third- party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring; • we, regulators, or IRBs /RECs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics of the product candidate, including where combination dosing of or with our product candidates results in serious adverse events or undesirable side effects, or due to

findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate; • marketing approval policies could change during the development period, rendering our data insufficient to obtain marketing approval; • statutes or regulations or site policies could be amended or new ones could be adopted; • changes could be adopted in the regulatory review process for submitted product applications; • the cost of clinical trials may be greater than we anticipate or we may have insufficient funds to complete a clinical trial; • the supply or quality of materials necessary to conduct clinical trials may be insufficient or inadequate or may be interrupted or impacted by supply chain challenges; • we may decide, or regulators may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical studies, or we may abandon product development programs; • we may fail to reach an agreement with regulators or IRBs / **RECs** regarding the scope, design, or implementation of our clinical trials, and the FDA or comparable foreign regulatory authorities may require changes to our study designs that make further study impractical or not financially prudent; • we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites; • patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study or clinical trial, increase the needed enrollment size for the clinical trial or extend its duration; • there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our current product candidates and any future product candidates; • the FDA or a comparable foreign regulatory authority may disagree with our study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug or biologic candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations; • the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries; • the FDA or comparable foreign regulatory authorities may disagree with our intended indications; • the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies; • the data collected from clinical trials of our current product candidates and any future product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an BLA or NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere; • the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our current product candidates and any future product candidates; and • we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development. Our development costs also will increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process. We will be required to obtain additional funds to complete clinical trials and prepare for possible commercialization. Significant delays relating to any preclinical or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our current product candidates and any future product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our current product candidates and any future product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of our current product candidates and any future product candidates. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed. Challenges enrolling patients in our clinical trials may delay **and or** prevent completion of clinical trials of our product candidates. Identifying and qualifying patients to participate in clinical trials is critical to our success. The timing of completion of our clinical trials depends in part on the speed at which we can recruit patients to participate in our clinical trials. Initiating and continuing clinical trials requires locating, enrolling and retaining sufficient numbers of eligible patients to participate in these trials. Patient enrollment requires initiation of clinical trial sites; accordingly, delays in initiation of sites exacerbate enrollment challenges. Public health challenges may impact our ability to initiate clinical sites and recruit, enroll and retain patients and divert healthcare resources away from clinical trials. In addition to the competitive trial environment, the eligibility criteria of our planned clinical trials limits the pool of available participants as we require that participants have specific, measurable characteristics to assure their cancer is severe enough but not too advanced for inclusion in a trial and exclude participants who have conditions that may increase the risk associated with participation in a trial. Additionally, the process of finding patients is costly. Delays in recruiting and conducting our clinical trials result when patients are unwilling to participate in our trials, which may delay our efforts to obtain regulatory approval of potential products. The enrollment of patients further depends on many factors, including: • the size of the patient population and process for identifying patients; • the eligibility criteria for the clinical trial in question; • the availability of an appropriate screening test, as necessary; • the perceived risks and benefits of the product candidate under study, including as a result of lack of efficacy or adverse events observed in similar or competing product candidates; • the efforts to facilitate timely enrollment in clinical trials; • the proximity and availability of clinical trial sites for prospective patients; • the design of the clinical trial; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • our ability to obtain and maintain patient consents; • reporting of preliminary results of any of our clinical trials, and / or reporting of results of clinical trials of our competitors; and • the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion. Our clinical trials compete with other clinical trials for product candidates that treat the same indications or are in the same therapeutic areas, and this competition may reduce the number and types of eligible patients available to us because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a competitor's clinical trial. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation of such patients in our clinical trials. We anticipate that our product candidates will be used in combination with third- party drugs or biologics ; **some of which are still in development**, and we have limited or no control over the supply, regulatory status, or regulatory

approval of such drugs or biologics. Our product candidates have the potential to be administered or co- formulated in combination with checkpoint inhibitor immunotherapies or other standards of care like chemotherapies, targeted therapies or radiotherapy. For example, ~~we are currently conducting a multi- arm Phase 1 /2a clinical trial of inupadenant as a single agent and in combination with pembrolizumab. In addition,~~ in collaboration with GSK, we are exploring the development of belrestotug with multiple combinations, including with dostarlimab. Our ability to develop and ultimately commercialize our product candidates used in combination with pembrolizumab or any other checkpoint inhibitor immunotherapies will depend on our ability to access such drugs or biologics on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that commercial relationships, including our collaborations with Merck and GSK, will provide us with a steady supply of such drugs or biologics on commercially reasonable terms or at all. Failure to maintain or enter into new successful commercial relationships, or the expense of purchasing checkpoint inhibitor immunotherapies or other comparator therapies, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed. Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. We are currently developing belrestotug, ~~inupadenant and~~ EOS- 984, **and EOS- 215** for use in combination with checkpoint inhibitor immunotherapies and with other therapies and may develop belrestotug, ~~inupadenant,~~ EOS- 984, **EOS- 215** or any future product candidates for use with other therapies. The FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. The results of such trials could show that any positive previous trial results are attributable to the combination therapy and not our product candidates. Moreover, following product approval, the FDA or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use, which may require us to work with a third party to satisfy such a requirement. Additionally, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product' s safety or efficacy profile, changes to the availability of the approved product, quality, manufacturing and supply issues, and changes to the standard of care. In the event that Merck, GSK or any other collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing such products. Additionally, should the supply of products from Merck, GSK or any other collaborator or supplier be interrupted, delayed or otherwise be unavailable to us, our clinical trials may be delayed. In the event we are unable to source an alternative supply, or are unable to do so on commercially reasonable terms, our business, financial condition, results of operations, stock price and prospects may be materially harmed. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future discovery and preclinical development programs and product candidates for specific indications may not yield any commercially viable products. Interim " top- line " and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and audit and verification procedures are required to validate the quality, reliability and integrity of our data and could result in material changes in the final data. From time to time, we may publish interim top- line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top- line results also remain subject to audit and verification procedures which are required to validate the quality, reliability and integrity of our data. These factors may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. We may not be able to file IND /**CTA** applications or IND /**CTA** amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or a comparable foreign regulatory authority may not permit us to proceed. The FDA or a comparable foreign regulatory authority may require us to file separate INDs /**CTAs** for additional clinical trials we plan to conduct with our current product candidates, belrestotug, ~~inupadenant, and~~ EOS- 984, **and EOS- 215**. We may not be able to file any additional INDs /**CTAs** on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND- enabling studies, including due to the impact of public health challenges on suppliers, study sites, or third- party contractors and vendors on whom we depend. Moreover, we cannot be sure that submission of an IND /**CTA** or submission of a trial to an IND will result in the FDA or comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that lead us to suspend or terminate clinical trials. Additionally, even if regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND /**CTA**, such regulatory authorities may change their requirements in the future. The FDA or comparable foreign regulatory authorities may require the analysis of data from trials assessing different doses of the product candidate alone or in combination with other therapies to justify the selected dose prior to the initiation of large trials in a specific indication. Any delays or failure to file INDs /**CTAs**, initiate clinical trials, or obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. We are subject to similar risks related to the review and authorization of our protocols and amendments by comparable foreign regulatory authorities. We are conducting clinical trials for product candidates outside the United States, and

the FDA and comparable foreign regulatory authorities may not accept data from such trials. We are conducting and in the future may conduct one or more clinical trials outside the United States, including in Europe and in Asia. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice, or ("GCP"), regulations. In general, the patient population for any clinical trials conducted outside the United States must be representative of the population for whom we intend to label the product candidate in the United States. Additionally, the FDA's clinical trial requirements, including applicable study design, sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, additional trials would be needed, which could be costly and time-consuming, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction. As an organization, we have never conducted pivotal clinical trials, and we may be unable to do so for any product candidates we may develop. We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA or comparable foreign regulatory authorities to market belrestotug, ~~inupadenant~~, EOS- 984, **EOS- 215**, or any future product candidate. Carrying out pivotal clinical trials is a complicated process. As an organization, we have not previously conducted any later stage or pivotal clinical trials. In order to do so, we will need to continue to expand our clinical development and regulatory capabilities, and we may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our pivotal clinical trials. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA or, NDA or MA submission and approval of belrestotug, ~~inupadenant~~, EOS- 984, **EOS- 215**, or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates. We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated. The development and commercialization of cancer immunotherapy products is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face competition with respect to our product candidates, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. A number of large biopharmaceutical and biotechnology companies currently market and sell products, or are pursuing the development of products, for the treatment of solid and liquid tumors. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization. While our product candidates are intended to be used in combination with other drugs or biologics with different mechanisms of action, if and when marketed they will compete with a number of drugs and biologics that are currently marketed or in development. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are easier to administer, or are less expensive alone or in combination with other therapies than products we may develop alone or in combination with other therapies. Our competitors also may obtain FDA or comparable foreign regulatory authorities' approval for their products more rapidly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected by insurers, government, or other third- party payor coverage decisions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products. Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in developing or acquiring technologies complementary to, or necessary for, our programs. If we are unable to successfully compete with these companies our business, financial condition, results of operations, stock price and prospects may be materially harmed. The size of the potential market for our product candidates is difficult to estimate and, if our assumptions are inaccurate, the actual market for our product candidates may be smaller than our estimates. The potential market opportunities for our product candidates are difficult to estimate and depend on the drugs with which our product candidates are co-administered or co- formulated and the success of competing therapies and therapeutic approaches. Our estimates of potential market opportunities are predicated on many assumptions that involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. New information may change the estimated incidence or prevalence of indications, and regulatory approvals, if received, may include limitations for use or contraindications that decrease the addressable patient population. If any of the assumptions proves to be inaccurate, the actual markets for our current product candidates and any future product candidates could be smaller than our estimates of the potential market opportunities. Negative developments in the field of immuno- oncology or in the ~~field of~~

specific cancer resistance mechanisms that we target, such as TIGIT or **the** adenosine pathway **therapeutics**, could damage public perception of our product candidates or negatively affect our business. The commercial success of our product candidates will depend in part on public acceptance of the use of cancer immunotherapies and **our the specific cancer resistance mechanisms of action and developments in that we target, such as** TIGIT or **the** adenosine pathway programs of other companies. Adverse events or disappointing results in clinical trials of our product candidates, or in clinical trials of similar products, as well as any other negative developments in the field of immuno- oncology, including in connection with competitor therapies, could reduce expectations regarding the potential success of our programs and potentially have a negative impact on collaborations. These events also could 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 or ineffective, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials or may discontinue their participation in our clinical trials. Negative developments could result in reduced probability of success of clinical trials involving our product candidates, challenges enrolling clinical trials, greater governmental regulation, stricter labeling requirements, and potential regulatory delays in the testing or approvals of our product candidates. If we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed. If we are successful in obtaining marketing approval from applicable regulatory authorities for our current or future product candidates, our ability to generate revenues from our product candidates will depend on our success in: • launching commercial sales, whether alone or in collaboration with others; • receiving an approved label with claims that are necessary or desirable for successful marketing and does not contain limitations that impede our ability to market the product; • creating market demand through marketing, sales and promotion activities; • hiring, training, and deploying a sales force or contracting with third parties to commercialize our product candidates in the United States; • manufacturing the product in sufficient quantities and at acceptable quality and cost to meet commercial demand; • establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms; • creating partnerships with, or offering licenses to, third parties to promote and sell our product candidates in foreign markets where we receive marketing approval; • maintaining patent and trade secret protection or regulatory exclusivity; • achieving market acceptance of our current product candidates or any future product candidates by patients, the medical community, and third- party payors; • favorable coverage and reimbursement from third party payors; • effectively competing with other therapies; and • maintaining a continued acceptable safety profile of our products. To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Risks related to government regulation Even if our development efforts are successful, we may not obtain regulatory approval for any product candidates in the United States or other jurisdictions, which would prevent us from commercializing our product candidates. Even if we obtain regulatory approval for our product candidates, any such approval may be subject to limitations, including with respect to the approved indications or patient populations, which may impair our ability to successfully commercialize our product candidates. We are not permitted to market, promote, or sell our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information for each therapeutic indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Even if our product candidates are approved, they may: • be subject to limitations on the indicated uses or patient populations for which they may be marketed, distribution restrictions, or other conditions of approval; • contain significant safety warnings, including boxed warnings, contraindications, and precautions; • not be approved with label statements necessary or desirable for successful commercialization; or • contain requirements for costly post- market testing and surveillance, or other requirements, including the submission of a REMS to monitor the safety or efficacy of the products. We have not previously submitted a BLA or NDA to the FDA, or a similar marketing application to comparable foreign regulatory authorities, for any product candidate, and we may not ultimately be successful in obtaining regulatory approval for claims that are necessary or desirable for successful marketing, or at all. The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. If we experience delays in obtaining required regulatory approvals, our ability to generate revenue may be materially impaired. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the discretion of regulatory authorities. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change and may vary among jurisdictions. These regulatory requirements may require us to amend our clinical trial protocols, conduct additional preclinical studies or clinical trials that may require regulatory or IRB /**REC** approval, or otherwise cause delays in the approval or rejection of an application. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which may materially harm our business, financial condition, results of operations, stock price and prospects. The FDA or a comparable foreign regulatory authority may determine that our product candidates have serious adverse events or undesirable side effects that delay or prevent their regulatory approval or commercialization. Serious adverse events or undesirable side effects caused by our product candidates could cause us, IRBs /**RECs**, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in enrollment challenges, discontinuation of trials, a more restrictive label, or delay or denial of marketing approval. We have identified in the past and may in the future identify serious adverse events suspected to be related to our product candidates. If concerns are raised regarding undesirable

side effects or serious adverse events identified during clinical or preclinical testing, including any dose-limiting toxicities, the FDA or comparable foreign regulatory authority may request additional data or information or order us to pause or cease further development, e. g., by issuing a clinical hold on ongoing or planned clinical trials, declining to approve the product candidate, or issuing a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate. The FDA or comparable foreign regulatory authorities, or IRBs /RECs and other reviewing entities, may also require, or we may voluntarily develop, strategies for managing adverse events during clinical development, which could include restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, reconsent of enrolled patients, or the monitoring of safety data by a data monitoring committee, among other strategies. Requests for additional data or information from the FDA or a comparable foreign regulatory authority also could result in substantial delays in the approval of our product candidates. Additionally, we may evaluate our product candidates in combination with one another, and safety concerns arising during a combination trial could negatively affect the individual development program of each candidate, as the FDA or comparable foreign regulatory authorities may require us to discontinue single-candidate trials until the contribution of each product candidate to any safety issues is better understood. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of a drug or biologic candidate may only be uncovered when a significantly larger number of patients are exposed to the drug or biologic candidate or when patients are exposed for a longer period of time. Later discovered undesirable side effects may further result in the imposition of a REMS, label revisions, post-approval study requirements, or other testing, and surveillance. If our product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially harm our business, financial condition, results of operations, stock price and prospects. Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to specific indications and conditions, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of our products for unapproved or "off-label" uses, or in a manner inconsistent with the approved labeling, resulting in damage to our reputation and business. We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA and comparable foreign regulatory authorities. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA or comparable foreign regulatory authority approval for desired uses or indications for our product candidates, we may not market or promote them for those indications and uses, referred to as off-label uses, and our business, financial condition, results of operations, stock price, prospects and reputation may be materially harmed. We also must sufficiently substantiate any claims that we make for our products, including claims comparing our products to other companies' products, and must abide by the FDA or comparable foreign regulatory authority's strict requirements regarding the content of promotion and advertising. While physicians may choose to prescribe products for uses that are not described in the product's labeling, we and any third parties engaged on our behalf are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA or comparable foreign regulatory authorities. If we market our medicines for off-label use, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. A company that is found to have promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Even if it is later determined that we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters. Even if our current product candidates and any future product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products. Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA and comparable foreign regulatory authorities, including requirements related to the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, applicable tracking and tracing requirements, export, import, advertising, marketing, and promotional activities. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with the FDA's cGMP, requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and GCPs for any clinical trials that we conduct post-approval. We and any of our suppliers or collaborators, including our CMOs, would be subject to periodic inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes. In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with our products, manufacturers, or manufacturing processes, or failure to comply with regulatory requirements either before or after approval, may yield various negative results, including: • restrictions on manufacturing, distribution, or marketing of such products; • restrictions on the labeling, including required additional warnings, such as boxed warnings, contraindications, precautions, and restrictions on the approved indication or use; • modifications to promotional pieces; • issuance of corrective information; • requirements to conduct post-marketing studies or other clinical trials; • clinical holds or termination of clinical trials; • requirements to establish or modify a

REMS or similar strategy; • changes to the way the product candidate is administered; • liability for harm caused to patients or subjects; • reputational harm; • the product becoming less competitive; • warning or untitled letters; • suspension of marketing or withdrawal of the products from the market; • regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product candidate; • refusal to approve pending applications or supplements to approved applications that we submit; • recalls of products; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • refusal to permit the import or export of our products; • product seizure or detention; • FDA or comparable foreign regulatory authority debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or • injunctions or the imposition of civil or criminal penalties, including imprisonment. We may seek orphan drug status for our product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced. We may seek orphan drug designation for some or all of our product candidates in orphan indications in which there is a medically plausible basis for the use of these products. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and 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 quantities of the product to meet the needs of patients with the rare disease or condition. **Similar regulatory risks may occur in foreign jurisdictions, such as the EU. Therefore, orphan designation may not be granted or maintained by the comparable regulatory authorities.** In addition, the FDA has expressed concerns regarding the regulatory considerations for orphan drug designation as applied to tissue agnostic therapies, and the FDA may interpret the federal Food, Drug and Cosmetic Act, as amended (~~C~~-or the "FD & C Act"), and regulations promulgated thereunder in a way that limits or blocks our ability to obtain orphan drug designation or orphan drug exclusivity, if our current product candidates and any future product candidates are approved, for our targeted indications. The FDA may reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. We may pursue Fast Track or Breakthrough Therapy designation by FDA. These designations may not actually lead to a faster development or regulatory review or approval process, and they do not assure FDA approval of any product candidates we may develop. FDA's Fast Track and Breakthrough Therapy designations programs are intended to expedite the development of certain qualifying products intended for the treatment of serious diseases and conditions. While we may seek Fast Track or Breakthrough Therapy designation, there is no guarantee that we will be successful in obtaining any such designation. Even if we do obtain such designation, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. Fast Track or Breakthrough Designation alone do not guarantee qualification for the FDA's priority review procedures. A Fast Track or Breakthrough Therapy designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. In addition, the FDA may withdraw Fast Track or Breakthrough Therapy designation if it believes that the designation is no longer supported by data from our clinical development program. If we are unable to successfully validate, develop, and obtain regulatory approval for companion diagnostic tests for our product candidates that require or would commercially benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates. In connection with the clinical development of our product candidates for certain indications, we may engage third parties to develop or obtain access to in vitro companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our product candidates. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory, and logistical challenges. The FDA and comparable foreign regulatory authorities regulate in vitro companion diagnostics as medical devices and, under that regulatory framework, likely will require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we or our collaborators may develop, which we expect will require separate regulatory clearance or approval prior to commercialization. Even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. Even if we are able to commercialize any product candidates, such drugs and biologics may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business. The regulations that govern regulatory approvals, pricing and reimbursement for new drugs and biologics vary widely from country to country. Some countries require approval of the sale price of a drug or biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product candidate, possibly for lengthy time periods, and negatively

impact the revenues we are able to generate from the sale of the product candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more of our product candidates, even if our product candidates obtain marketing approval. In the United States, the availability and adequacy of coverage and reimbursement by third-party payors, including governmental healthcare programs such as Medicare and Medicaid, as well as private health insurance, will likely be essential for most patients to be able to afford our product candidates, assuming regulatory approval. There is significant uncertainty related to third party payor coverage and reimbursement of newly-approved products. No uniform policy for coverage and reimbursement for products exists among third-party payors. Coverage and reimbursement for products can differ significantly from payor to payor and coverage and reimbursement by one payor does not guarantee coverage and reimbursement by another payor. Third-party payors increasingly are limiting coverage and utilization of pharmaceutical products and challenging prices charged for pharmaceutical products and services. Assuming we obtain coverage for a product by a third-party payor, the third-party payor may implement utilization management controls, such as requiring pre-approval before our product will be covered for a particular patient, which may limit access to our product. In addition, the reimbursement rates may not be adequate or may require co-payments that patients find unacceptably high. Net prices for our products may be reduced by mandatory discounts or rebates that we are required to provide to certain government healthcare programs or private payors or by discounts we negotiate with third party payors. If coverage is limited, access to our products is subject to utilization management controls or reimbursement is inadequate, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on our product candidates. Healthcare reform measures may have a material adverse effect on our business and results of operations. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. In the United States, numerous legislative and regulatory initiatives seek to contain healthcare costs. We expect that federal and state healthcare reform measures will limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. See "Government Regulation- Healthcare Reform". Limitations in coverage or reduction in reimbursement from Medicare or other government programs may result in similar actions from private payors, which may adversely affect our future profitability. Our relationships with healthcare providers, customers, and third-party payors will be subject to applicable fraud and abuse, privacy and price reporting and payment and other healthcare laws and regulations, which could expose us to significant administrative, civil, and criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from government healthcare programs, contractual damages, reputational harm, and diminished profits and future earnings. Our arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that constrain the business or financial arrangements and relationships through which we research, market, sell, and distribute our product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following: • the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid; • the federal civil and federal false claims laws and civil monetary penalty laws, including the False Claims Act which can be enforced through civil whistleblower or qui tam actions, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; • HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended, and its implementing regulations which also establish privacy and security standards applicable to healthcare providers and other entities and their business associates that limit the use and disclosure of individually identifiable healthcare information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information; • the Federal Food, Drug and Cosmetic Act, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples; • federal laws, including the Medicaid Drug Rebate Program, which require pharmaceutical manufacturers to calculate, report and certify certain complex calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs; • the so-called "federal sunshine" law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians, certain non-physician practitioners and teaching hospitals to the federal government for re-disclosure to the public; and • federal consumer protection and unfair competition laws and regulations, which broadly regulate marketplace activities and that potentially harm consumers.

• also, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply to claims reimbursed by private payors as well as government programs regardless of reimbursement. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government's and / or pharmaceutical industry's voluntary compliance guidelines, impose specific restrictions on interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Other state laws may require pharmaceutical companies to file reports relating to pricing and marketing information and state and local laws may require the registration of pharmaceutical sales representatives. The distribution of drugs and biological products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Finally, there are state laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA. Many of these laws and regulations also contain ambiguous requirements or require administrative guidance for implementation. Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. We have entered into certain advisory board and consulting agreements with physicians, including some who are compensated in the form of stock or stock options, who may influence the ordering or use of our product candidates, if approved. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices may not comply with such laws and regulations. If our operations were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. Even if we successfully defend against an action against us for violation of law, the action and our defense could nonetheless cause us to incur significant legal expenses; divert our management's attention from the operation of our business and otherwise impair our reputation and business. Failure to comply with environmental, health, and safety laws and regulations, may subject us to fines or penalties, or 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 and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. 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. Our business activities are subject to the Foreign Corrupt Practices Act, or ("FCPA"), and similar anti-bribery and anti-corruption laws. Expanding our business activities outside of the United States, including our clinical trial efforts, subjects us to the FCPA and similar anti-bribery or anti-corruption laws, regulations, or rules of other countries. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-United States 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. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-United States governments. Additionally, in many other countries, the healthcare 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 will be subject to regulation under the FCPA. Failure by our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, to comply with applicable laws and regulations, particularly given the high level of complexity of these laws could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, 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 as well as difficulties in manufacturing or continuing to develop our products, 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. Risks related to reliance on third parties We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. Failure by these third parties to satisfactorily carry out their contractual duties in compliance with the applicable regulatory requirements or to meet expected deadlines may delay and increase the costs of our development programs, adversely impacting our business and prospects. We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are, and expect to remain, dependent on third parties to conduct our ongoing preclinical and clinical trials and any future preclinical and clinical trials of our product candidates. The timing of the initiation and completion of these trials, therefore, is partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators, and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. We are not able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with

the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities **as a trial sponsor as defined by GCP**. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the **NCAs Competent Authorities** of the **EEA Member States of the European Economic Area**, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators **and**, clinical trial sites, **and CROs**. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the 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. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and / or repeat clinical trials, which would delay or prevent marketing. CROs, clinical trial investigators or other third parties on which we rely may fail to devote adequate time and resources to our development activities or perform as contractually required. The performance of our CROs may also be interrupted by public health challenges, including due to prioritization of resources toward such challenges or high turnover rates. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements **or predefined quality standards**, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash **and /** or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our current product candidates or any future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products. If our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we endeavor to carefully manage our relationships with our CROs and other third parties, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. We may not realize the benefits of our collaborations, alliances or licensing arrangements, including our collaboration with GSK for the global development of belrestotug. We may form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates. Currently we are party to the GSK Collaboration Agreement, pursuant to which we share with GSK responsibility and costs for the global development of belrestotug. Under the GSK Collaboration Agreement, in the United States we and GSK will jointly commercialize and equally split profits while outside of the United States GSK will receive an exclusive license for commercialization. We are also eligible to receive tiered double digit royalty payments up to 20 % during a customary royalty term. Our collaboration with GSK is not without risks, which include the following: • Our control over the development and commercialization activities of belrestotug may be limited; • GSK's commercialization activities outside the United States may adversely impact our own efforts in the United States; • Relying on GSK to commercialize any products containing or comprising belrestotug that obtain regulatory approval, may cause us to receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects; • GSK may compete with us, or collaborate with our competitors; • GSK may not properly maintain or defend our intellectual property rights or may improperly use our intellectual property or proprietary information; • GSK may fail to meet its obligations under the GSK Collaboration Agreement ~~to~~ to apply sufficient efforts at developing and commercializing belrestotug, or to comply with applicable legal or regulatory requirements; • GSK may terminate the GSK Collaboration Agreement, which could damage perception of our product candidates, slow down our execution and timelines, and negatively affect the clinical development or commercialization of belrestotug; and • disputes may arise between us and GSK that cause the delay or termination of the development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources. The occurrence of any of the risks detailed above may materially adversely affect our business and our results of operations. Future collaborations will likely be subject to similar risks as outlined above. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. We may not realize the benefits of collaborations related to companion diagnostic tests for our therapeutic product candidates. We intend to rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that may require such tests. If we enter into collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity / specificity,

analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. A diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company 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 therapeutic candidates. We rely on third parties to manufacture our product candidates, and we expect to continue to rely on third parties for the clinical as well as any future commercial supply of our product candidates. The development of our product candidates, and the commercialization of any approved products, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient clinical or commercial quantities of such product candidates or products, fails to do so at acceptable quality levels or prices, or fails to achieve or maintain satisfactory regulatory compliance. We do not currently have, and we do not plan to build, the infrastructure or capability internally to manufacture product candidates for use in the conduct of our **preclinical and** clinical trials or, if approved, for commercial supply. We rely on, and expect to continue to rely on, contract manufacturing organizations, or CMOs. Reliance on third- party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We do not control the manufacturing processes of the CMOs we contract with and are dependent on those third parties for the production of our product candidates in accordance with relevant applicable regulations such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. In complying with the manufacturing regulations of the FDA and comparable foreign regulatory authorities, we and our third- party suppliers must spend significant time, money, and effort in the areas of design and development, testing, production, record- keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of products and shutting down of production. We and any of these third- party suppliers also may be subject to inspections by the FDA or comparable foreign regulatory authorities. If any of our third- party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize our product candidates could suffer significant interruptions. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. If our CMOs fail to perform their obligations for any reason, or if there are any disruptions at our CMOs, or impacts on our CMOs, due to fire, natural hazards, vandalism, public health challenges, or any other events, our manufacturing capacity could be significantly interrupted. We currently do not have alternative production plans in place or disaster- recovery facilities available. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as we build facilities or locate alternative suppliers and seek and obtain necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all. If changes to CMOs occur, then there also may be changes to manufacturing processes inherent in the setup of new operations for our product candidates and any products that may obtain approval in the future. Any such changes could require the conduct of bridging studies before we can use any materials produced at new facilities or under new processes in clinical trials or, for any products reaching approval, in our commercial supply. Further, business interruption insurance may not adequately compensate us for any losses that may occur and we would have to bear the additional cost of any disruption. For these reasons, a significant disruptive event of any CMOs could have drastic consequences, including placing our financial stability at risk. Our product candidates and any drugs that we may develop may compete with other product candidates and drugs for access to manufacturing facilities. We may not be able to enter into similar commercial arrangements with other manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our clinical or commercial demand for any of our product candidates, we could experience delays in our planned clinical studies or commercialization. For example, public health challenges, such as the COVID-19 pandemic, may impact our ability to procure sufficient supplies for the development of our ~~current and future~~ product candidates, and the extent of such impacts will depend on the severity and duration of the public health challenge and the actions undertaken to address it. We could be unable to find alternative suppliers of acceptable quality and experience that can produce and supply appropriate volumes at an acceptable cost or on favorable terms. Moreover, our suppliers are subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, would significantly delay our clinical trials and, for any product candidates that reach approval, the commercialization of our products, which would materially adversely affect our business, financial condition and results of operation. **A portion of our manufacturing of our product candidates takes place in China through third- party manufacturers. We are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China, including tariffs and sanctions on China or any of our China- based third- party manufacturers. In addition, there has been increased governmental focus, including legislative proposals, in the United States on the role of Chinese companies in the life sciences industry. For example, in 2024 a bi- partisan bill was introduced into the U. S. Congress known as the BIOSECURE Act, which, if enacted into law in its most recent form, may restrict our ability to use services provided WuXi Apttec, WuXi Biologics, and WuXi STA (Chinese companies from whom we receive**

development and manufacturing services) in the performance of contracts with or grants from the U. S. government. To the extent these, or other companies with whom we contract, are the subject of U. S. governmental focus, we may need to transition to other providers, which could be costly and may delay the development and commercialization of our products.

The manufacture of biologics is complex, and our third- party manufacturers may encounter difficulties in production. If any of our third- party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity, and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping, and quality control and testing, may result in lot failures, product recalls, or spoilage. Changes to the manufacturing process often require preclinical and clinical data showing the comparable identity, strength, quality, purity, or potency of the products before and after such changes. Microbial, viral or other contaminations may require closure of facilities for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients also can lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. In addition, risks associated with large scale manufacturing for clinical trials or commercial scale include, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency, and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, our manufacturers may not be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product, or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Our reliance on third parties requires us to share our trade secrets, which increases the possibility of competitor discovery, misappropriation, or disclosure. Because we rely on third parties to research and develop and to manufacture our product candidates, we must share trade secrets. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements, or other similar agreements with our advisors, employees, third- party contractors, and consultants. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with often expect to be granted rights to publish data arising out of such collaboration, and any joint research and development programs may require us to share trade secrets under the terms of our research and development or similar agreements. Sharing trade secrets and other confidential information increases the risk that such information becomes known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors, and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Risks related to our limited operating history, financial position and capital requirements Our limited operating history may make it difficult for you to evaluate our business and to assess our future viability. We are a clinical- stage immuno- oncology company with a limited operating history. We have not yet demonstrated our ability to successfully conduct or complete any clinical trials, obtain marketing approvals, manufacture a commercial- scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing, and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future. Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We are still in the early stages of development of our product candidates. Belrestotug ~~is and inupadenant are each~~ in ongoing **Phase 3 and** Phase 2 clinical trials and EOS- 984 is in ~~a~~ **an ongoing** Phase 1 clinical trial. We have no products licensed for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we: • conduct preclinical studies and clinical trials for our current and future product candidates; • continue our research and development efforts and submit INDs for future product candidates; • seek marketing approvals for

any product candidates that successfully complete clinical trials; • build commercial infrastructure to support sales and marketing for any approved product candidates; • scale up external manufacturing and distribution capabilities for clinical and, if approved, commercial supply of our product candidates; • expand, maintain and protect our intellectual property portfolio; • hire additional clinical, regulatory and scientific personnel and scale up such capabilities; and • operate as a public company. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. 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, seek approval for, and market additional product candidates. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenues that are significant or large enough to achieve profitability. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges 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 stockholders' equity. We have never generated any revenue from product sales and may never be profitable. Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from any product sales. We have no products approved for commercial sale, and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including: • initiating and completing research regarding, and preclinical and clinical development of our product candidates; • obtaining marketing approvals for product candidates for which we complete clinical trials; • developing a sustainable and scalable manufacturing process for our product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties; • launching and commercializing our product candidates, either directly or with a collaborator or distributor; • obtaining market acceptance of our product candidates as viable treatment options; • addressing any competing technological and market developments; • identifying, assessing, acquiring and developing new product candidates; • negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter; obtaining, maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and • attracting, hiring, and retaining qualified personnel. We will require additional financing to achieve our goals, 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 or commercialization efforts. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical development of our product candidates and to conduct IND- enabling studies for additional product candidates. If approved, we will require significant additional amounts in order to launch and commercialize our product candidates. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. Accordingly, we will need to raise substantial additional capital in connection with our continuing operations. Our future capital requirements depend on many factors, including: • the scope, progress, results, and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials; • the timing of, and the costs involved in, obtaining marketing approvals for our product candidates if clinical trials are successful; • the extent to which we develop, in- license or acquire other product candidates and technologies; • the number and development requirements of other product candidates we may pursue; • the success of the GSK collaboration and any other collaborations; • the cost of commercialization activities for any approved product, including marketing, sales and distribution costs; • the cost of manufacturing our product candidates for clinical trials in preparation for marketing approval and commercialization; • our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements; • the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; • the timing, receipt, and amount of sales of, or royalties on, future approved products, if any; and • the emergence of competing cancer therapies and other adverse market developments. Until we can generate sufficient product 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, including through our at- the- market ; of ("ATM ") program, debt financings, collaborations, strategic alliances, licensing and grant arrangements and other marketing or distribution arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. Further, our ability to raise additional capital and maintain liquidity may be adversely impacted by potential worsening global economic conditions and the ongoing disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from inflationary pressures among other macroeconomic concerns. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our research and development initiatives. We could be required to seek additional collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition, and results of operations and cause the price of our common stock to decline. Risks related to intellectual property If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and research programs. We seek to protect our proprietary position by filing patent applications in the

United States and abroad related to our novel discoveries and technologies that are important to our business, however, we cannot predict: • if and when patents may issue based on our patent applications; • the scope of protection of any patent issuing based on our patent applications; • whether the claims of any patent issuing based on our patent applications will protect our current product candidates or any future product candidates and their intended uses or prevent others from commercializing competitive technologies or products; • whether or not third parties will find ways to invalidate or circumvent our patent rights; • whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; and / or • whether we will need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose. Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and / or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. Additionally, we may fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. We also cannot be certain that the claims in our pending patent applications directed to our product candidates and / or technologies will be considered patentable by the United States Patent and Trademark Office, or the USPTO, or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the “prior art,” information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position 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. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries. We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope, or expiration of a third-party patent which might adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims, or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent’s prosecution history. We must correctly interpret the relevance or the scope of a patent or a pending application, determine whether our products are covered by a third-party patent, predict whether a third party’s pending application will issue with claims of relevant scope, and determine the expiration date of any patent in the United States or abroad that we consider relevant. Failure to do so may negatively impact our ability to develop and market our products. We may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated. From time to time we may be required to license technology from additional third parties to further develop or commercialize our current product candidates or any future product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our current product candidates or any future product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our current product candidates or any future product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations. We may not be able to protect our intellectual property rights throughout the world. Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our current product candidates or any future product candidates throughout the world would be prohibitively expensive. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, 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. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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. Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current product candidates or any future product candidates. Our success is heavily dependent on intellectual property, particularly patents. However, the patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and in recent years has been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, that have increased uncertainties as to the ability to obtain and enforce patent rights in the future. Changes in either the patent laws or interpretation of the patent laws in the United

States and other countries could increase the uncertainties and costs. For example, in September 2011 the Leahy-Smith America Invents Act (or the "America Invents Act"), was signed into law and included a number of significant changes to United States patent law as then existed. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. Such avenues include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. After March 2013, under the America Invents Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the United States Congress, the United States courts, the USPTO and the relevant law-making bodies in other countries, 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 and future patents. We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for some of our technology and current product candidates or any future product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our current product candidates or any future product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Patent terms may be inadequate to protect our competitive position on our current product candidates or any future product candidates for an adequate amount of time. Patent rights are of limited duration. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Even if patents covering our current product candidates or any future product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, 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. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. We may become involved in lawsuits alleging that we have infringed the intellectual property rights of third parties or to protect or enforce our patents or other intellectual property, which litigation could be expensive, time consuming and adversely affect our ability to develop or commercialize our product candidates. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, which may not be able to do. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may find that competitors are infringing our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke

these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. We could be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our current product candidates or any future product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and / or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Risks related to our business operations, employee matters, taxes, litigation, and managing growth We expect to expand our development, regulatory, and operational capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As we advance our research and development programs and as we continue to operate as a public company, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of management and operations, clinical development, quality, regulatory affairs and, if any of our product candidates receive marketing approval, sales, marketing, and distribution. To manage our anticipated future growth, we must: • identify, recruit, integrate, retain, and motivate additional qualified personnel; • manage our development efforts effectively, including the initiation and conduct of clinical trials for our current product candidates or any future product candidates, both as monotherapy and in combination with other intra-portfolio product candidates; and • improve our operational, financial, and management controls, reporting systems and procedures. Our future financial performance and our ability to develop, manufacture, and commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert financial and other resources, and 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 our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. 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 the services of our founder, Michel Detheux, Ph. D., who serves as our Chief Executive Officer and President, and on our other executives. Although we have entered into employment agreements with each of our executives, such agreements are not for a specific term and each executive may terminate their employment with us at any time. We are not aware of any present intention of any of these key personnel to leave us. We do not maintain "key person" insurance for any of our executives or employees. We believe that any of our executives would be difficult to replace. Our industry has experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive biopharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management skills and experience. Although we conduct our research and development in Belgium, our headquarters ~~with management~~ is located in Massachusetts, and we plan on expanding our clinical development activities in the Boston area, a region that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. We may not be able to attract or

retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical companies. Many of our competitors have greater financial and other resources, different risk profiles and a longer history in the industry than we do, and may provide higher compensation, more diverse opportunities and / or better opportunities for career advancement. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. ~~For example, our interim Chief Medical Officer is a consultant.~~ Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Any or all of these factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our current product candidates or any future product candidates and to grow our business and operations as currently contemplated. Information system failures or unauthorized or inappropriate use of or access to our information systems risk disclosure of confidential or proprietary information, including personal data, and could damage our reputation, and subject us to significant financial and legal exposure. We rely on information technology systems that we or our third- party providers operate to collect, process, transmit, and store electronic information in our day- to- day operations. In connection with our product discovery, research and development efforts, we collect and use sensitive data, including intellectual property, proprietary or confidential business information, and a variety of personal data, such as names, mailing addresses, email addresses, phone numbers and clinical trial information. The secure maintenance of this information is critical to our operations, business strategy and reputation. Cyber- attacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial- of- service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. Cyber- attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance. We are required to expend significant resources in an effort to protect against security incidents and may be required or choose to spend additional resources or modify our business activities, particularly where required by applicable data privacy and security laws or regulations or industry standards. Although we have implemented security measures, there can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would not be successful or damaging. Despite the implementation of security measures, our information technology systems, and those of our contractors and consultants who process information on our behalf or have access to our systems, are vulnerable to damage or interruption from computer viruses, unauthorized or inappropriate access or use, natural disasters, terrorism, war, and telecommunication and electrical failures. Such events could cause interruption of our operations. For example, the loss of pre- clinical trial data or data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory filings and development efforts, as well as delays in the commercialization of our products, and significantly increase our costs. To the extent that any disruption, security breach or unauthorized or inappropriate use or access to our systems were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, including but not limited to patient, employee or vendor information, we could incur substantial remediation costs, notification and disclosure obligations to affected individuals and government agencies, regulatory enforcement, potential lawsuits and liability under data protection laws, our reputation may be damaged, and the development and potential commercialization of our product candidates could be delayed, any of which could have a material adverse effect on our business, financial condition, and results of operations. Compliance with global privacy and data security requirements could result in additional costs and liabilities or inhibit our ability to collect and process data globally, and our failure to comply with data protection laws and regulations could lead to government enforcement actions, fines, and other harms which would cause our business and reputation to suffer. Evolving state, federal and foreign laws, regulations and industry standards regarding privacy and security apply to our collection, use, retention, protection, disclosure, transfer and other processing of personal data. Privacy and data protection laws may be interpreted and applied differently from country to country and may create inconsistent or conflicting requirements, which increases the costs incurred by us in complying with such laws, which may be substantial. For example, the GDPR, which became effective in May 2018, imposes a broad array of requirements for processing personal data, including elevated disclosure requirements regarding collection and use of such data, restrictions on the transfer of personal data, requirements that companies allow individuals to exercise data protection rights such as their rights to obtain copies or demand deletion of personal data held by those companies, limitations on retention of information, and disclosure of significant data breaches to individuals and regulators, among other things. The GDPR provides for substantial penalties for non- compliance of up to the greater of € 20 million or 4 % of global annual revenue for the preceding financial year. From January 1, 2021, the GDPR has been retained in the UK, as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of Section 3 of the European Union (Withdrawal) Act 2018, as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (SI 2019 / 419) (“ UK GDPR ”), alongside the UK’ s Data Protection Act 2018. The UK GDPR mirrors the fines under the GDPR, i. e., fines up to the greater of € 20 million (£ 17. 5 million) or 4 % of global turnover. Our efforts to comply with the GDPR, the UK GDPR and other privacy and data protection laws impose significant costs and challenges that are likely to increase over time, and we may be exposed to substantial penalties or litigation related to violations of existing or future data privacy laws and regulations. Privacy laws and regulations are also expanding in the U. S. Comprehensive state privacy laws are either in effect or have been enacted in a number of states, and similar laws are being considered in several other states, as well as at the federal and local levels. As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations. The evolving patchwork of differing state and federal privacy and data security laws increases the cost and complexity of operating our business and increases our exposure to liability, including from third- party litigation and regulatory investigations, enforcement, fines, and penalties. Failure by us or third- party CMOs, CROs or other contractors or consultants

to comply with United States and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and / or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Unfavorable global economic and trade conditions could adversely affect our business, financial condition, or results of operations. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, pandemics or other public health challenges, political instability and military or other conflicts, including Russia's invasion of Ukraine, the Israel- Hamas war and the potential for a wider European, Middle East or global conflict, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party CMOs, may negatively impact our supply chain, manufacturing costs or productivity, the economies in geographies in which we operate, or our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. It may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. We maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, our insurance may not be sufficient to satisfy any damages and losses. If our facilities or the manufacturing facilities of our third-party CMOs are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets and global trade. We conduct, and we expect to continue to conduct, portions of our clinical trials outside the United States, and unfavorable economic conditions resulting in the weakening of the United States dollar would make those clinical trials more costly to operate. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, such as a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy, including supply chain disruptions, labor shortages and persistent inflation, could also strain our suppliers, possibly resulting in supply disruption, and could negatively impact our access to liquidity and banking relationships. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. ~~A portion of our manufacturing of our product candidates takes place in China through third-party manufacturers. A significant disruption in the operation of those manufacturers, a trade war or political unrest in China could materially adversely affect our business, financial condition and results of operations. We currently contract manufacturing operations to third parties, and clinical quantities of our product candidates are currently manufactured by these third parties outside the United States, including in China. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, whether as a result of a natural disaster, a pandemic or other public health challenges, or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates. Furthermore, since some of our manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China, including sanctions on China or any of our China-based third-party manufacturers. For example, a trade war could lead to tariffs on the chemical intermediates we use that are manufactured in China and in 2017, the United States proposed tariffs of 25% on raw ingredients for pharmaceuticals, such as the active pharmaceutical ingredients for our proposed product candidates. Any of these matters could materially and adversely affect our business and results of operations. Any recall of the manufacturing lots or similar action regarding our product candidates used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in China.~~ We may be exposed to significant foreign exchange risk. We incur portions of our expenses, and may in the future derive revenues, in a variety of currencies. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. Fluctuations in currency exchange rates have had, and will continue to have, an impact on our results as expressed in United States dollars. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the euro. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows. Our operations subject us to potentially adverse tax consequences. We are required to file income tax returns in the **United States**, U.S. and Belgium, which requires us to interpret the applicable tax laws and regulations in effect in such jurisdictions. Furthermore, significant judgment is required in evaluating our tax positions,

including our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. Our interpretation or application of accounting policies may be questioned by the relevant tax authorities, and the relevant tax laws and regulations, or the interpretation thereof, including through tax rulings, by the relevant tax authorities, may be subject to change. Any adverse outcome of such a review or change, including any adverse resolution of one or more uncertain tax positions, may lead to adjustments in the amounts recorded in our financial statements, and could have a materially adverse effect on our operating results and financial condition. Changes in United States federal income tax or Belgian tax laws and regulations could adversely affect our business and financial condition. We are subject to taxes in the **United States**, ~~U. S.~~ and Belgium, as well as laws and regulations regarding taxes, levies, and other charges in different countries. These tax rules, which are subject to change, affect tax liabilities imposed in respect of our assets, income, and operations, including transactions with third parties, affiliates and employees. Dealings and other intercompany transactions between current group companies and former group companies as well as additional companies that may form part of our group in the future are subject to transfer pricing regulations imposed by jurisdictions in which such companies are resident and can affect the income tax liability of each company. Our effective tax rates and liability for tax in Belgium, the United States, and other jurisdictions could be adversely affected by changes in tax laws, treaties and regulations, both internationally and domestically, or the interpretation thereof by the relevant tax authorities, including changes to the innovation income deduction, the research and development tax credit, the corporate income tax base, the wage withholding tax incentive for qualified research and development personnel in Belgium and other tax incentives and the implementation of new tax incentives. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock. If we are unable to use Belgian tax loss carryforwards to reduce future taxable income or benefit from the favorable Belgian tax legislation, our business, results of operations and financial condition may be adversely affected. At December 31, ~~2023~~ **2024**, we had an estimated cumulative carry forward tax losses of \$ ~~64.61~~ **19** million in Belgium. Under the current legislation these are available to carry forward and offset against certain future taxable income for an indefinite period in Belgium. If we are unable to use tax loss carryforwards to reduce future taxable income, our business, results of operations and financial condition may be adversely affected. As a company active in research and development in Belgium we have benefited from the availability of the Belgian research and development tax credit, which can offset the Belgian corporate income tax due or it can be refunded if not used within ~~four~~ **three** subsequent taxable periods. We also expect to benefit from the innovation income deduction, ~~or ("IID")~~, in Belgium, which allows net profits attributable to revenue from patented products (or products for which the patent application is pending), among other things, be taxed at a lower rate than other revenues. The tax authorities may challenge our eligibility for, or our calculation of, certain tax reductions and / or deductions in respect of our research and development activities and, should the Belgian tax authorities be successful, we may be liable for additional corporate income tax, and penalties and interest related thereto, which could have a significant impact on our results of operations and future cash flows. We are subject to certain covenants as a result of certain non-dilutive financial support we have received to date. We have been awarded grants from the Walloon Region, a federal region of Belgium, and the European Union to fund research and development activities. Several of the grants include no obligation to repay the amount received under the grants. We own the intellectual property rights that result from the research programs or with regard to a patent covered by these grants. Subject to certain exceptions, however, we cannot grant to third parties, by way of license, transfer or otherwise, any right to use the patents or research results without the prior consent of the Walloon Region. In addition, certain grants require that we exploit the patent in the countries where the protection was granted and to make an industrial use of the underlying invention. In case of bankruptcy, liquidation or dissolution, the rights to the patents covered by the patent grants will be assumed by the Walloon Region by operation of law unless the grants are reimbursed. Furthermore, we would lose our qualification as a small or medium-sized enterprise, the grants subsidies would terminate and no additional expenses would be covered by such patent grants. Two of the grants, which are referred to as recoverable cash advance grants, ~~or ("RCAs")~~, include a potential obligation to repay the amount received under the grants. Under the RCAs, the Walloon Region ~~will has provide~~ **provided** us with up to € 23.2 million for our research and development programs for belrestotug and inupadenant. We ~~are no longer receiving~~ **received the last of the** payments ~~from~~ **from** for each of these grants ~~in the year ended December 31, 2022,~~ and ~~therefore~~ did not receive any payments for these grants in ~~2023~~ **2024**. We must repay 30 % of the amount received under the grants unless we decide ~~not to~~ **abandon** ~~pursue commercial development or our out licensing of~~ **intellectual property rights in** the drug candidate, inform the Walloon Region of our decision and justify our decision based upon the failure of the program, and transfer the intellectual property rights to the Walloon Region. This is referred to as the fixed repayment. In addition, in the event that we receive revenue from products or services related to the results of the program, we will have to pay to the Walloon Region a 0.33 % royalty on revenue resulting from the first RCA grant and a 0.15 % royalty on revenue resulting from the second RCA grant (increased from 0.12 % effective December 2021). The maximum amount payable to the Walloon Region under each grant, including the fixed repayment, the royalty on revenue, and the interest thereon, is twice the amount of funding received. Subject to certain exceptions, we cannot grant to third parties, by way of license or otherwise, any right to use the results without the prior consent of the Walloon Region. We also need the consent of the Walloon Region to transfer an intellectual property right resulting from the research programs or a transfer or license of a prototype or installation. Obtaining such consent from the Walloon Region could give rise to their review of the applicable financial terms. The RCAs also contain provisions prohibiting us from conducting research within the scope of the RCAs for any third parties. This prohibition is applicable beyond the research phase and decision phase and could restrict our ability to enter into research-related collaboration or partnership agreements with respect to those programs. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit our commercialization of any product candidates that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human

clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in: • delay or termination of clinical trials; • decreased demand for any product candidates or products that we may develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial subjects; • initiation of investigations by regulators; • significant costs to defend the related litigation and diversion of management's time and our resources; • substantial monetary awards to study subjects or patients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; and • the inability to commercialize any products that we may develop. We may be at an increased risk of securities class action litigation. Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. Risks related to ownership of our common stock The trading price of our common stock has been volatile. The trading price of our common stock has been highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this " Risk factors " section, these factors include: • the results of our ongoing, planned or future preclinical studies, clinical trials or clinical development programs; • the commencement, enrollment, or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates; • adverse results or delays in preclinical studies and clinical trials; • our decision to initiate a clinical trial, not to initiate a clinical trial, or to pause or terminate an existing clinical trial; • any delay in our regulatory filings or any adverse regulatory decisions, including clinical holds or failure to receive regulatory approval of our product candidates; • changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals; • adverse developments concerning our manufacturers or our manufacturing plans; • our inability to obtain adequate product supply for any licensed 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; • 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; • changes in the structure of healthcare payment systems; • our ability to effectively manage our growth; • 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 intellectual property or stockholder litigation; • general political and economic conditions; and • other events or factors, many of which are beyond our control. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Raising additional capital and future issuances of our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates, and could cause our stock price to fall. We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, expanded research and development activities, and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions, including through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements, at prices and in a manner we determine from time to time. If we sell common stock, convertible securities, or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock. In addition, such sales, or the perception that such sales may occur, could cause our stock price to decline. To the extent that we raise additional capital through the sale of equity or convertible debt securities, including sales of our common stock pursuant to the Sales Agreement ~~with Cowen and Company LLC (Cowen), dated May 10, 2023 (Sales Agreement)~~, our stockholder's ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us. 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. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur. Our principal stockholders and management own a significant percentage of our stock and

will be able to exert significant influence over matters subject to stockholder approval. Our executive officers, directors, and 5 % stockholders beneficially owned approximately ~~57-53.8-0~~ % of our outstanding voting stock as of December 31, ~~2023-2024~~. These stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all 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 that our stockholders may feel are in their best interest. We are an emerging growth company **and a smaller reporting company**, and the reduced disclosure requirements applicable to emerging growth **companies and smaller reporting** companies may make our common stock less attractive to investors. We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, as amended ~~, or ("~~ Sarbanes- Oxley Act ~~")~~, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following 2020, the year in which we completed our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least \$ 1. 235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non- affiliates to exceed \$ 700 million as of the prior June 30th, and (2) the date on which we have issued more than \$ 1 billion in non- convertible debt during the prior three- year period. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. **We are also a " smaller reporting company ", meaning that the market value of our stock held by non- affiliates was less than \$ 700 million and our annual revenue was less than \$ 100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non- affiliates is less than \$ 250 million or (ii) our annual revenue was less than \$ 100 million during the most recently completed fiscal year and the market value of our stock held by non- affiliates is less than \$ 700 million. Even after we no longer qualify as an emerging growth company, we may still qualify as a " smaller reporting company, " which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements as an emerging growth company, including regarding executive compensation in our periodic reports and proxy statements. In addition, as long as we are a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports on Form 10- K.** We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. 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, defer 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; • 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 a majority of the members of our board of 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; • a requirement of approval of not less than two- thirds of all outstanding shares of our voting stock and not less than two- thirds of the outstanding shares of each class entitled to vote thereon as a class to amend specific provisions of our certificate of incorporation; • a requirement of approval of not less than two- thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action; and • the authority of our 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, 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 acquirers 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 stockholders to elect directors of their choosing or cause us to take other corporate actions they 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 certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our amended and restated 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 any state law claim for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim 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 ~~(, or the "Delaware Forum Provision ")~~. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act ~~(, or the "Federal Forum Provision ")~~, as our principle office is located in Cambridge, Massachusetts. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. We recognize that the Delaware Forum Provision and the Federal Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts 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 may be more or less favorable to us than our stockholders. If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed. Ensuring that we have adequate internal control over financial reporting in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with our IPO, we began the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We are currently subject to compliance with Section 404 (a) of the Sarbanes-Oxley Act, and have implemented a framework of internal controls to comply with this regulation. We have structured our finance team with finance and accounting personnel with certain skill sets that we need as a public company. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities. Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.