Risk Factors Comparison 2024-02-27 to 2023-02-28 Form: 10-K

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This Annual Report contains forward- looking information based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward- looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, operating results, financial condition and the trading price of our common stock. You should carefully consider these risk factors, together with all of the other information included in this Annual Report as well as our other publicly available filings with the Securities and Exchange Commission. Summary of Selected Risks Our business is subject to numerous risks and uncertainties, of which you should be aware before making a decision to invest in our securities. These risks and uncertainties include, among others, the following: • We ~~may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any of our product candidates. • We~~ are currently developing several product candidates. If we are unable to successfully complete clinical development of, obtain regulatory approval for and commercialize our product candidates, our business prospects will be significantly harmed. • Revumenib **and axatilimab** has undergone limited clinical testing and we may fail to show that it is well tolerated and provides sufficient clinical benefit for patients. • ~~Axatilimab has undergone limited clinical testing and we may fail to show that it is well tolerated and provides a sufficient clinical benefit for patients. •~~ Interim top- line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data ~~becomes~~ **become** available and are subject to audit and verification procedures that could result in material changes ~~in~~ **to** the final data **. • We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any of our product candidates** . • Incyte may fail to perform its obligations as expected under the collaboration or may deprioritize its investment to further develop and commercialize axatilimab. • If we are or our collaborators are unable to enroll patients in clinical trials, these clinical trials may not be completed on a timely basis or at all. • The regulatory approval processes of the FDA and foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would harm our business. • Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community to be commercially successful. • We rely on third- party suppliers as well as Incyte to manufacture and distribute our clinical drug supplies for our product candidates, we intend to rely on third parties for commercial manufacturing and distribution of our product candidates and we expect to rely on third parties for manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates. • Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties. • Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial scope of their approved use, or result in significant negative consequences following any marketing approval. • We have incurred net losses since our inception, except 2021, and anticipate that we will continue to incur net losses for the foreseeable future. • We currently have no source of product revenue and may never achieve or maintain profitability. • We will require additional capital to finance our planned operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of, or obtain regulatory approval for our existing product candidates or develop new product candidates. • If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market. • We may not be able to protect our intellectual property rights throughout the world. • The market price of our stock may be volatile and you could lose all or part of your investment. • We may sell additional equity or debt securities or enter into other arrangements to fund our operations, which may result in dilution to our stockholders and impose restrictions or limitations on our business. Risks Related to Our Business and Industry Our financial success will depend substantially on our ability to effectively and profitably commercialize our product candidates. In order to commercialize our product candidates, we will be required to obtain regulatory approvals by establishing that each of them is sufficiently safe and effective. The clinical and commercial success of our product candidates will depend on a number of factors, including the following: • the initiation, cost, timing, progress and results of our research and development activities, clinical trials and preclinical studies; • timely completion of any future clinical trials of revumenib and axatilimab; • interruption of key clinical trial activities, in connection with public health threats or any future geopolitical tensions, such as the ongoing war between Russia and Ukraine **and the war in Israel** ; • whether we are required by the FDA or foreign regulatory authorities to conduct additional clinical trials prior to receiving marketing approval; • the prevalence and severity of adverse drug reactions in any of our clinical trials; • the ability to demonstrate safety and efficacy of our product candidates for their proposed indications and the timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities; • successfully meeting the endpoints in the clinical trials of our product candidates; • achieving and maintaining compliance with all applicable regulatory requirements; • the potential use of our product candidates to treat various cancer indications and fibrotic diseases; • the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments; • the effectiveness of our own or our potential strategic collaborators' marketing, sales and distribution strategy and operations in the United States and abroad; • the ability of our collaboration partner and of third- party contract manufacturers to produce trial supplies and to develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP; • our ability to successfully commercialize our product candidates in the United States and abroad, whether alone or in collaboration with others; **• our ability to prevent any significant disruptions of our information technology systems and protect the security of our data;** and • our ability to enforce our intellectual property rights in and to our product candidates. If we fail to

obtain regulatory approval for our product candidates, we will not be able to generate product sales, which will have a material adverse effect on our business and our prospects. **Revumenib has undergone limited clinical testing and we may fail to show that it is well tolerated and provides sufficient clinical benefit for patients.** Research suggests that certain acute leukemias, such as **lysine methyltransferase 2A rearranged, or** KMT2Ar **, acute myeloid or lymphoid** ~~leukemias~~ **leukemia, AML or ALL,** and nucleophosmin 1, or NPM1, mutant ~~acute myeloid leukemia, or~~ AML, are driven by the interaction of menin, a nuclear protein involved in transcription, with the N- terminus of ~~MLL1~~ **KMT2A** protein ~~, a histone methyl transferase~~ . In NPM1 mutant AML the interaction with menin occurs via the wild type ~~MLL1~~ **KMT2A** protein, and in KMT2Ar acute ~~leukemias~~ **leukemia** , the interaction occurs via a mutant form of ~~MLL1~~ **KMT2A** , a fusion protein known as ~~MLLr~~ **KMT2Ar** . ~~MLLr~~ **KMT2Ar** results from a rare, spontaneous fusion between the N- terminus of the **KMT2A gene** ~~mixed lineage leukemia protein- 1, or MLL1,~~ and a host of signaling molecules and nuclear transcription factors. This fusion produces an aberrant transcription program that drives leukemic transformation. In pre- clinical animal models, small molecule inhibitors of the menin- ~~MLLr~~ **KMT2Ar** interaction, such as revumenib, which bind to, and block the interaction of menin with either ~~MLLr~~ **KMT2A rearranged** or ~~MLL1~~ **wildtype** , have demonstrated deep and durable single agent treatment effects in multiple leukemic xenograft models harboring ~~MLL~~ **KMT2A** fusions or NPM1 mutations. Our strategy for developing revumenib is to conduct a Phase 1 / 2 clinical trial in r / r patients with KMT2Ar and NPM1 mutant acute leukemias and determine if the observed clinical efficacy supports further development. The Phase 1 portion of the trial is assessing the safety, tolerability and pharmacokinetics of revumenib, and seeks to establish a recommended Phase 2 dose. It is open label, and we have released and may in the future release results from time to time that reflect small numbers of patients which may not be accurately predictive of safety or efficacy results later in the trial or in subsequent trials. The Phase 2 portion is evaluating the efficacy of revumenib across three expansion cohorts enrolling pediatric and adult R / R patients with KMT2Ar ~~acute lymphoblastic leukemia, or~~ ALL, KMT2Ar AML, and NPM1 mutant AML **. In October 2023, we announced positive topline data in patients with R / R KMT2Ar acute leukemia and that we have submitted an NDA under the FDA' s RTOR program. Neither breakthrough therapy designation nor RTOR review change the standards for approval and may not ultimately expedite the approval process or lead to approval** . While we believe that we have established sufficient efficacy to warrant **an NDA submission and** continued development in these indications, we ~~have~~ **may** not yet **have** sufficiently demonstrated a favorable risk- benefit of revumenib in patients. Axatilimab has undergone limited clinical testing and we may fail to show that it is well tolerated and provides ~~a~~ **sufficient** clinical benefit for patients. Preclinical studies suggest that CSF- 1 / CSF- 1R signaling may be the key regulatory pathway involved in the expansion and infiltration of donor derived macrophages that mediate the disease processes involved in cGVHD and other fibrotic or inflammatory diseases. Nonclinical studies and analysis of patient samples indicates that the cGVHD inflammatory disease process is a result of a complex interaction between host and donor immune cells including B cells, and regulatory T cells with M2 differentiated macrophages in target tissue appearing to represent the common distal mediator of fibrosis. Therefore, we hypothesize that a CSF- 1R signal inhibitor such as axatilimab may play a meaningful role as a monotherapy agent in the treatment of cGVHD. ~~Our approach is to conduct~~ **In 2018, we commenced** a Phase 1 / 2 clinical trial with axatilimab in subjects with active cGVHD who ~~have~~ **had** failed at least two prior lines of therapy. Following our end of Phase 1 meeting with the FDA, we ~~have~~ aligned on a regulatory path for axatilimab for the treatment of cGVHD and commenced a pivotal Phase 2 clinical trial, AGAVE- 201, to assess the safety and efficacy of different doses and schedules of axatilimab for the treatment of patients with cGVHD. **In July 2023, we announced that AGAVE- 201 met its primary endpoint across all three doses in the trial. In January 2024, we announced that, along with Incyte, we have submitted a BLA, the previous December.** While we believe that we have established sufficient efficacy to warrant **a BLA submission and** continued development in this indication, we ~~have~~ **may** not yet **have** sufficiently demonstrated a favorable risk- benefit of axatilimab in patients. ~~Interim top- line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.~~ From time to time, we may publish interim top- line or preliminary data from our clinical trials. For example, in **each of** ~~April and December 2021 and in~~ November 2022 **and 2023** , we announced interim data from our Phase 1 / 2 clinical trial of revumenib. Interim data 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 data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Preliminary or top- line data may include, for example, data regarding a small percentage of the patients enrolled in a clinical trial, and such preliminary data should not be viewed as an indication, belief or guarantee that other patients enrolled in such clinical trial will achieve similar results or that the preliminary results from such patients will be maintained. As a result, interim and preliminary data 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. Before obtaining marketing approval from regulatory authorities for the sale of any of our product candidates, we or our collaborators must conduct extensive trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and difficult to design and implement, can take many years to complete and is inherently uncertain as to the outcome. A failure of one or more trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not accurately predict the success of later trials, and interim results of a trial do not necessarily predict final results. ~~A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials.~~ We are dependent upon our collaboration with Incyte to further develop and commercialize axatilimab. If we or Incyte fail to perform as expected the potential for us to generate future revenues under the collaboration could be significantly reduced, the development and / or commercialization of axatilimab may be terminated or substantially delayed, and our business could be adversely affected. We are subject to numerous risks related to

the Incyte Collaboration Agreement to collaborate on the development and commercialization of axatilimab. For example, there is no assurance that the parties will achieve any of the regulatory development or sales milestones, that we will receive any future milestone or royalty payments under the collaboration agreement. Incyte' s activities may be influenced by, among other things, the efforts and allocation of resources by Incyte, which we cannot control. If Incyte does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, manufacturing, regulatory approval, and commercialization efforts related to axatilimab could be delayed or terminated. In addition, our license with Incyte may be unsuccessful due to other factors, including, without limitation, the following: • Incyte may terminate the agreement for convenience upon 90 or 180 days' notice depending on whether or not the parties have commercialized axatilimab in an indication in the respective territory; • Incyte may change the focus of its development and commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to axatilimab • Incyte may, within its commercially reasonable discretion, choose not to develop and commercialize axatilimab in all relevant markets or for one or more indications, if at all; and • if Incyte is acquired during the term of our collaboration, the acquirer may have competing programs or different strategic priorities that could cause it to reduce its commitment to our collaboration or to terminate the collaboration. We cannot ensure that the potential strategic benefits and opportunities expected from this collaboration with be realized on our anticipated timeline or at all. If we or our collaborators are unable to enroll patients in clinical trials, these clinical trials may not be completed on a timely basis or at all. The timely completion of clinical trials largely depends on patient enrollment. Many factors affect patient enrollment, including: • the impact of public health crises, or geopolitical tensions, such as the ongoing war between Russia and Ukraine **and the war in Israel** ; • perception about the relative efficacy of our product candidates versus other compounds in clinical development or commercially available; • evolving standard of care in treating cancer patients; • the size and nature of the patient population, especially in the case of an orphan indication, we are pursuing; • the number and location of clinical trial sites enrolled; • competition with other organizations or our own clinical trials for clinical trial sites or patients; • the eligibility and exclusion criteria for the trial; • the design of the trial; • ability to obtain and maintain patient consent; and • risk that enrolled subjects will drop out before completion. As a result of the above factors, there is a risk that our or our collaborators' clinical trials may not be completed on a timely basis or at all. We may be required to relinquish important rights to and control over the development and commercialization of our product candidates to our current or future collaborators. Our collaborations, including any future strategic collaborations we enter into, could subject us to a number of risks, including: • we may be required to undertake the expenditure of substantial operational, financial and management resources; • we may be required to issue equity securities that would dilute our existing stockholders' percentage of ownership; • we may be required to assume substantial actual or contingent liabilities; • we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates; • strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing; • strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs; • strategic collaborators may not commit adequate resources to the marketing **, sales** and distribution of our product candidates, limiting our potential revenues from these products; • disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management' s attention and consumes resources; • strategic collaborators may experience financial difficulties; • strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation; • business combinations or significant changes in a strategic collaborator' s business strategy may also adversely affect a strategic collaborator' s willingness or ability to complete its obligations under any arrangement; • strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and • strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing, our product candidates. We may explore strategic collaborations that may never materialize or may fail. We periodically explore a variety of possible strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations can be complicated and time consuming to negotiate and document. We may enter into strategic collaborations that we subsequently no longer wish to pursue, and we may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them. The FDA and comparable foreign regulatory authorities extensively and rigorously regulate and evaluate the manufacture, testing, distribution, advertising and marketing of drug products prior to granting marketing approvals with respect to such products. This approval process generally requires, at minimum, testing of any product candidate in preclinical studies and clinical trials to establish its safety and effectiveness, and confirmation by the FDA and comparable foreign regulatory authorities that any such product candidate, and any parties involved in its manufacturing, testing and development, complied with current Good Manufacturing Practices, or ~~GMP~~ **cGMP** , current Good Laboratory Practices ~~, or GLP,~~ and current Good Clinical Practices ~~, or GCP~~ , regulations, standards and guidelines during such manufacturing, testing and development. The time required to obtain approval by the FDA and foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. We

have not obtained regulatory approval for any of our product candidates and it is possible that we will never obtain regulatory approval for our existing product candidates or any future product candidates. In addition, our product candidates could fail to receive regulatory approval from the FDA or foreign regulatory authorities for other reasons, including but not limited to: • failure to demonstrate that our product candidates are effective for their proposed indication and have an acceptable safety profile; • failure of clinical trials to meet the primary endpoints or level of statistical significance required for approval; • failure to demonstrate that the clinical and other benefits of a product candidate outweigh any of its safety risks; • disagreement with our interpretation of data from preclinical studies or clinical trials; • disagreement with the design, size, conduct or implementation of our or our collaborators' trials; • the insufficiency of data collected from trials of our product candidates to support the submission and filing of an NDA, BLA or other submission or to obtain regulatory approval; • failure to obtain approval of the manufacturing and testing processes or facilities of third- party manufacturers with whom we contract for clinical and commercial supplies; • receipt of a negative opinion from an advisory committee due to a change in the standard of care regardless of the outcome of the clinical trials; or • changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval. The FDA or foreign regulatory authorities may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or may cause us to decide to abandon our development program. Even if we were to obtain approval, regulatory authorities may approve one or more of our product candidates for a more limited patient population than we request, may grant approval contingent on the performance of costly post- marketing trials, may impose a risk evaluation and mitigation strategy, or REMS, or foreign regulatory authorities may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of one or more of our product candidates and impose burdensome implementation requirements on us, or may approve it with a label that does not include the labeling claims necessary or desirable for the successful commercialization of one or more of our product candidates, all of which could limit our ability to successfully commercialize our product candidates **. Moreover, if adopted in the form proposed, the recent European Commission proposals to revise the existing European Union, or EU, laws governing authorization of medicinal products may result in a decrease in data and market exclusivity for our product candidates in the EU** . Even if our product candidates receive regulatory approval, they may not gain sufficient market acceptance among physicians, patients, healthcare payors and others in the medical community. Our commercial success also depends on coverage and adequate reimbursement by third- party payors, including government payors, which may be difficult or time- consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our product candidates. The degree of market acceptance will depend on a number of factors, including: • the efficacy and safety profile as demonstrated in trials; • the timing of market introduction as well as competitive products; • the clinical indications for which the product candidate is approved; • acceptance of the product candidate as a safe and effective treatment by physicians, clinics and patients; • the potential and perceived advantages of our product candidates over alternative treatments; • the cost of treatment in relation to alternative treatments; • pricing and the availability of coverage and adequate reimbursement by third- party payors, including government authorities; • relative convenience and ease of administration; • the frequency and severity of adverse events; • the effectiveness of sales and marketing; and • unfavorable publicity relating to our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue to become or remain profitable. We ~~rely on third- party suppliers as well as Incyte to manufacture and distribute our clinical drug supplies for our product candidates, we intend to rely on these parties for commercial manufacturing and distribution of our product candidates and we expect to rely on third parties for manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates. We~~ do not currently have, nor do we plan to acquire, the infrastructure or capability to manufacture or distribute preclinical, clinical or commercial quantities of drug substance or drug product, including our existing product candidates. While we expect to continue to depend on third- party manufacturers and Incyte for the foreseeable future, we do not have direct control over the ability of these parties to maintain adequate manufacturing capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. In ~~additional~~ -- **addition** , public health crises, may impact the ability of our existing or future manufacturers to perform their obligations to us. We are dependent on our third- party manufacturers and Incyte for compliance with cGMPs and for manufacture of both active drug substances and finished drug products. Facilities used by our third- party manufacturers and Incyte to manufacture drug substance and drug product for commercial sale must be approved by the FDA or other relevant foreign regulatory agencies pursuant to inspections that will be conducted after we submit our NDA or relevant foreign regulatory submission to the applicable regulatory agency. If our third- party manufacturers or Incyte cannot successfully manufacture materials that conform to our specifications and / or the strict regulatory requirements of the FDA or foreign regulatory agencies, they will not be able to secure and / or maintain regulatory approval for their manufacturing facilities. Furthermore, these third- party manufacturers are engaged with other companies to supply and / or manufacture materials or products for such companies, which also exposes our third- party manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a third- party manufacturers' facility. If the FDA or a foreign regulatory agency does not approve these facilities for the manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would impede or delay our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Even if we obtain regulatory approval for our product candidates, they would be subject to ongoing requirements by the FDA and foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post- market information. The FDA and foreign regulatory authorities will continue to monitor closely the safety profile of any product even after approval. If the FDA or

foreign regulatory authorities become aware of new safety information after approval of a product candidate, they may require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on its indicated uses or marketing, or impose ongoing requirements for potentially costly post- approval studies or post- market surveillance. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including withdrawal of the product from the market or suspension of manufacturing, or we may recall the product from distribution. If we, or our third- party manufacturers, fail to comply with applicable regulatory requirements, a regulatory agency may: • issue warning letters or untitled letters; • mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners; • require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; • seek an injunction or impose civil or criminal penalties or monetary fines; • suspend or withdraw regulatory approval; • suspend any ongoing clinical trials; • refuse to approve pending applications or supplements to applications filed by us; • suspend or impose restrictions on operations, including costly new manufacturing requirements; or • seize or detain products, or refuse to permit the import or export of products. The occurrence of any event or penalty described above may inhibit our ability to commercialize and generate revenue from the sale of our product candidates. Advertising and promotion of any product candidate that obtains approval in the United States is heavily scrutinized by the FDA' s Office of Prescription Drug Promotion, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, other government agencies and the public. While physicians may prescribe products for off- label uses as the FDA and other regulatory agencies do not regulate a physician' s choice of drug treatment made in the physician' s independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off- label uses of products for which marketing clearance has not been issued. Companies may only share truthful and not misleading information that is otherwise consistent with a product' s FDA approved labeling. Violations, including promotion of our products for unapproved (or off- label) uses, may be subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the government. Additionally, foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval in their respective jurisdictions. In the United States, engaging in the impermissible promotion of our products for off- label uses can also subject us to false claims litigation under federal and state statutes, which can lead to administrative, civil and criminal penalties, damages, monetary fines, disgorgement, individual imprisonment, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, curtailment or restructuring of our operations and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include, but are not limited to, the federal civil False Claims Act, which allows any individual to bring a lawsuit against an individual or entity, including a pharmaceutical or biopharmaceutical company on behalf of the federal government alleging the knowing submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment or approval by a federal program such as Medicare or Medicaid. These False Claims Act lawsuits against pharmaceutical or biopharmaceutical companies have increased significantly in number and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices, including promoting off- label drug uses involving fines in excess of $ 1. 0 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from participation in Medicare, Medicaid and other federal and state healthcare programs. If we, or any partner that we may engage, do not lawfully promote our approved products, we may become subject to such litigation, which may have a material adverse effect on our business, financial condition and results of operations. Undesirable side effects caused by our product candidates could cause the interruption, delay or halting of the trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other foreign regulatory authorities. Results of the clinical trials may reveal a high and unacceptable severity and prevalence of side effects or other unexpected characteristics. In such event, the trials could be suspended or terminated, or the FDA or foreign regulatory authorities could deny approval of our product candidates for any or all targeted indications. Drug- related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects. Additionally, if our product candidates receive marketing approval, and we or others later identify undesirable side effects, a number of potentially significant negative consequences could result, including: • we may suspend marketing of, or withdraw or recall, the product; • regulatory authorities may withdraw approvals; • regulatory authorities may require additional warnings on the product labels; • the FDA or other regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about the product; • the FDA may require the establishment or modification of a REMS or foreign regulatory authorities may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of the product and impose burdensome implementation requirements on us; • regulatory authorities may require that we conduct post- marketing studies; • we could be sued and held liable for harm caused to subjects or patients; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates for use in targeted indications or otherwise materially harm its commercial prospects, if approved, and could harm our business, results of operations and prospects. Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States. In order to market and sell our product candidates in other jurisdictions, we must obtain separate marketing approvals for those jurisdictions and comply with their numerous and varying regulatory requirements. We may not obtain foreign regulatory approvals on a timely basis, or at all. The approval procedure varies among countries and can involve

additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, product reimbursement approvals must be secured before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Our failure to obtain approval of our product candidates by foreign regulatory authorities may negatively impact the commercial prospects of such product candidates and our business prospects could decline. Also, if regulatory approval for our product candidates is granted, it may be later withdrawn. If we fail to comply with the regulatory requirements in international jurisdictions and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential for our product candidates will be harmed and our business may be adversely affected. We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. Even if any of our product candidates received regulatory approval, such product candidates would face competition from other therapies in the relevant indication. For example, chronic graft versus host disease has historically been managed by off- label treatments. However, in the past several years, the FDA has approved three drugs, ibrutinib (Imbruvica ®), belomosidil (Rezurock ®) and ruxolitinib (Jakafi ®), for use in patients with cGVHD after failure of one or more lines of systemic therapy. All three of these drugs may compete with axatilimab in patients diagnosed with cGVHD. Revumenib is being developed for the treatment of R / R adult and pediatric patients with KMT2Ar ALL, KMT2Ar AML and NPM1 mutant AML. At this time, there are no drugs approved for these defined populations and patients are managed using the standard of care treatment regimens developed for general AML and ALL populations. While there are other agents in early development for similar populations, revumenib has the potential to be the first defined therapy for patients with KMT2Ar ALL, KMT2Ar AML and / or NPM1 mutant AML. ~~Many of our existing~~ **Existing** or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Our competitors may be more successful than us in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective or more effectively marketed and sold than any drug we may commercialize and may render our product candidates obsolete or non- competitive before we can recover the expenses of developing and commercializing any of our product candidates. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. We believe that our ability to successfully compete will depend on, among other things: • the efficacy and safety profile of our product candidates relative to marketed products and product candidates in development by third parties; • the time it takes for our product candidates to complete clinical development and receive marketing approval; • our ability to commercialize our product candidates if they receive regulatory approval; • the price of our product candidates, including in comparison to branded or generic competitors; • whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare; • our ability to manufacture commercial quantities of our product candidates if they receive regulatory approval; and • our ability to negotiate preferential formulary status for our product candidates. Even if we obtain regulatory approval of our product candidates, the availability **, commercial formulary placement,** and price of our competitors' products could limit the demand and the price we are able to charge. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment, or if physicians switch to other new drug or biologic products or choose to reserve our drugs for use in limited circumstances **. Certain of our investigational products may require companion diagnostics in certain indications. Failure to successfully develop, validate and obtain regulatory clearance or approval for such tests could harm our product development strategy or prevent us from realizing the full commercial potential of our investigational products. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as a medical device and may require separate regulatory authorization prior to commercialization. Certain of our revumenib clinical trials include the use of an investigational or laboratory developed diagnostic test to help identify eligible patients. We currently do not have any plans to develop diagnostic tests internally. We are therefore dependent on the sustained cooperation and effort of third- party collaborators in developing and, if our investigational products are approved for use only with an approved companion diagnostic test, obtaining approval and commercializing these tests. If these parties are unable to successfully develop companion diagnostics for our investigational products, or experience delays in doing so, the development of our investigational products may be adversely affected and we may not be able to obtain marketing authorization for these investigational products. Furthermore, our ability to market and sell, as well as the commercial success, of any of our investigational products that require a companion diagnostic will be tied to, and dependent upon, the receipt of required regulatory authorization and the continued ability of such third parties to make the companion diagnostic commercially available on reasonable terms in the relevant geographies. Any failure to develop, validate, obtain and maintain marketing authorization and supply for a companion diagnostic we need may harm our business prospects** . We are dependent on UCB Biopharma Sprl, or UCB, to comply with the terms of our license agreement for axatilimab. Our commercial success also depends upon our ability to develop, manufacture, market and sell axatilimab. We have a worldwide, sublicensable, exclusive license to axatilimab pursuant to a license agreement with UCB. Certain of the rights licensed to us under the UCB license agreement are in- licensed by UCB from third parties. We are

dependent on UCB maintaining the applicable third- party license agreements in full force and effect, which may include activities and performance obligations that are not within our control. If any of these third- party license agreements terminate, certain of our rights to develop, manufacture, commercialize or sell axatilimab may be terminated as well. The occurrence of any of these events could adversely affect the development and commercialization of axatilimab, and materially harm our business. Our employees, consultants and collaborators may engage in misconduct or other improper activities, including insider trading and non- compliance with regulatory standards and requirements. We are exposed to the risk that our employees, consultants, distributors, and collaborators may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates the regulations of the FDA and non- U. S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of pharmaceuticals, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations. We must attract and retain additional highly skilled employees in order to succeed. To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical, commercial and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the pharmaceutical and biopharmaceutical industries is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality candidates than what we have to offer. If we are unable to continue to attract and retain high- quality personnel, the rate and success at which we can discover and develop product candidates and our business will be limited. Even if we commercialize our product candidates, they or any other product candidates that we develop, may become subject to unfavorable pricing regulations or third- party coverage or reimbursement practices, which could harm our business. Our ability to successfully commercialize our existing product candidates, or any other product candidates that we develop, will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third- party payors, including government healthcare programs, private health insurers, pharmacy benefit managers, managed care plans and other organizations. Third- party payors determine which medications they will cover and establish reimbursement levels. Third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third- party payors are requiring that drug companies provide them with predetermined rebates and discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Limitation on coverage and reimbursement may impact the demand for, or the price of, and our ability to successfully commercialize any product candidates that we develop. There may be significant delays in obtaining adequate coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, marketing, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Private payors often follow decisions by **Center for Medicare & Medicaid Services, or** CMS, regarding coverage and reimbursement to a substantial degree. However, one payor' s determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support

for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. The regulations that govern marketing approvals, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we may obtain marketing approval for our product candidates in a particular country **,** but be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment even if our product candidates obtain marketing approval. There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication, that it will be considered cost effective by third- party payors, that coverage and an adequate level of reimbursement will be available, or that third- party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably **. Even if favorable coverage status and adequate reimbursement rates are attained, less favorable coverage policies and reimbursement rates may be implemented in the future.** Current and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain. 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 any product candidate for which we obtain marketing approval. For example, then President Obama signed into law the Affordable Care Act. Among other cost containment measures, the Affordable Care Act established an annual, nondeductible fee on any entity that manufactures or imports branded prescription drugs and biologic agents, a Medicare Part D coverage gap discount program, and a formula that increased the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision that repealed, effective January 1, 2019, the tax- based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " On June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket costs through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, which began in 2013, and due to subsequent legislative amendments to the statute, will remain in effect through ~~2031~~ **2032** unless additional Congressional action is taken ~~. Under current legislation, the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequester~~ . Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which ended the use of the statutory formula and established a quality payment program, also referred to as the Quality Payment Program. ~~In November 2019~~ **Under both APMs and MIPS** , **performance data collected each performance year will affect Medicare** ~~CMS issued a final rule finalizing the changes to the Quality Payment~~ **payments in later years** ~~Program. At this time~~ , **including potentially reducing** ~~the full impact to overall physician reimbursement as a result of the introduction of the Quality Payment~~ **payments** ~~Program remains unclear~~ . Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several, Presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, in July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to President Biden' s executive order, on September 9, 2021, **the U. S. Department of Health and Human Services, or** HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (i) directs the Secretary of HHS to negotiate the price of certain high- expenditure, single- source drugs and biologics covered under Medicare Part B and Medicare Part D, and subjects drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated " maximum fair price " under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions ~~will~~ take effect

progressively starting in fiscal year 2023 **. On August 29** , ~~although~~ **2023, HHS announced** ~~they~~ **the** ~~may~~ **list of the first ten drugs that will** be subject to **price negotiations, although the Medicare drug price negotiation program is currently subject to** legal challenges. ~~Further,~~ **In response to** the Biden administration ~~released an additional~~ **' s October 2022** executive order **,** on ~~October~~ **February** 14, ~~2022~~ **2023** , ~~directing~~ HHS ~~to~~ **released a** report **outlining** ~~on how the three Center for Medicare and Medicaid Innovation can be further leveraged to test~~ new models for **testing by the CMS Innovation Center which will be evaluated on their ability to** ~~lowering~~ **lower** ~~drug~~ **the** ~~costs~~ **cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act. On December 8, 2023, the National Institute of Standards and Technology published** for ~~Medicare~~ **comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor** ~~and~~ **an** ~~Medicaid beneficiaries~~ **agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework** . At the state level, legislatures have increasingly passed and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing **. For example, on January 5, 2024, the FDA approved Florida' s Section 804 Importation Program, or SIP, proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs** . We expect these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. For example, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. We are in the process of building our sales, marketing and distribution infrastructure. In order to market any approved product candidate in the future, we must build our sales, marketing, distribution, managerial and other non- technical capabilities or make arrangements with third parties to perform these services, as we do not presently have all of these capabilities. To develop our internal sales, distribution and marketing capabilities, we must invest significant amounts of financial and management resources in the future. For drugs where we decide to perform sales, marketing and distribution functions ourselves, we could face a number of challenges, including that: • we may not be able to attract and build an effective marketing or sales organization; • the cost of establishing, training and providing regulatory oversight for a marketing or sales force may not be justifiable in light of the revenues generated by any particular product; • our direct or indirect sales and marketing efforts may not be successful; and • there are significant legal and regulatory risks in drug marketing and sales that we have never faced, and any failure to comply with all legal and regulatory requirements for sales, marketing and distribution could result in enforcement action by the FDA or other authorities that could jeopardize our ability to market the product or could subject us to substantial liabilities. Alternatively, we may rely on third parties to launch and market our product candidates, if approved. We may have limited or no control over the sales, marketing and distribution activities of these third parties and our future revenue may depend on the success of these third parties. Additionally, if these third parties fail to comply with all applicable legal or regulatory requirements, the FDA or another governmental agency could take enforcement action that could jeopardize their ability and our ability to market our product candidates. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product candidates. We face an inherent risk of product liability exposure related to the testing of our product candidates in human trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or other products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for our product candidates; • termination of clinical trial sites or entire trial programs; • injury to our reputation and significant negative media attention; • withdrawal of trial participants; • significant costs to defend the related litigation; • substantial monetary awards to trial subjects or patients; • diversion of management and scientific resources from our business operations; and • the inability to commercialize any products that we may develop. While we currently hold trial liability insurance coverage consistent with industry standards, this may not adequately cover all liabilities that we may incur. We also may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise in the future. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates, but we may be unable to obtain commercially reasonable product liability insurance. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and financial condition. Our relationships with healthcare providers, customers and third- party payors will be subject to applicable anti- kickback, fraud and abuse, transparency and other healthcare laws and regulations as well as privacy and data security laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, exclusion from participation in government healthcare programs, curtailments or restrictions of our operations, administrative burdens and diminished profits and future earnings **.** Healthcare providers, including physicians and third- party payors play a primary role in the

recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct clinical research and market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following: • the federal Anti- Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, or any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid **; • the federal Anti- Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other.; • the Affordable Care Act amended the intent requirement of the federal Anti- Kickback Statute so that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation** ; • the federal false claims, including the federal civil False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, and civil monetary penalties laws, which prohibit 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; • the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, also imposes obligations on covered entities, including certain health care providers, health plans and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; • the federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program to report annually to CMS information related to " payments or other transfers of value " made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require manufacturers to report pricing information regarding certain drugs; state and local laws that require the registration of pharmaceutical sales representatives; state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and federal, state, and foreign laws that govern the privacy and security of other personal information, including federal and state consumer protection laws, state data security laws, and data breach notification laws (a data breach affecting sensitive personal information, including health information, could result in significant legal and financial exposure and reputational damages). Efforts to ensure that our business arrangements with third parties and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time- consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any physician or other healthcare provider or entity with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government- funded healthcare programs. ~~Significant~~ **We are subject to stringent and evolving U. S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties;**

disruptions of **our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences. In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or collectively, process, personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third- party data, business plans, transactions, clinical trial data and financial information or collectively, sensitive data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws). For example, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. For more information regarding risks associated with HIPAA, please refer to the section above that discusses risks associated with healthcare laws and regulations. In the past few years, numerous U. S. states — including California, Virginia, Colorado, Connecticut, and Utah — have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, or CPRA and collectively, CCPA, applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $ 7, 500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws may impact (possibly significantly) our business activities depending on how it is interpreted, should we become subject to the CCPA in the future. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties upon whom we rely. Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union' s General Data Protection Regulation, or EU GDPR, and the United Kingdom' s GDPR, or UK GDPR, impose strict requirements for processing personal data. For example, under GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR or, in each case, 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. We may be subject to new laws governing the privacy of consumer health data, including reproductive, sexual orientation, and gender identity privacy rights. For example, Washington' s My Health My Data Act, or MHMD, broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws. Our employees and personnel may occasionally use generative artificial intelligence, or AI, technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross- border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area, or EEA, and the United Kingdom, or UK, have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA' s standard contractual clauses, the UK' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or**

degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations. In addition to data privacy and security laws, we are bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We also publish privacy policies, marketing materials, and other statements regarding data privacy and security and if these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences. Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- action claims) and mass arbitration demands; additional reporting requirements and / or oversight; bans on processing personal data (including clinical trial data); and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. If our information technology systems **, or ~~or~~ our** data ~~security incidents~~ **are or were compromised, we** could **experience adverse consequences** ~~result~~ **resulting** ~~in significant financial~~ **from such compromise** , ~~legal,~~ **including but not limited to** regulatory ~~,~~ **investigations or actions; fines and penalties; disruptions of our** business ~~and~~ **operations;** reputational harm ~~to us~~ **; loss of revenue or profits; and other adverse consequences** . We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive ~~information~~ **data** , ~~including intellectual property, proprietary business information, personal information~~ and **, as a result, we and** ~~other~~ -- **the** ~~confidential information. It is critical~~ **third parties upon which we rely face a variety of evolving threats** that **could cause security incidents** ~~we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information~~ . We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third- party vendors who may or could have access to our computer networks **and** ~~, our confidential information or~~ **our sensitive data** ~~the confidential information of third parties that is in our possession~~ . In addition, those third- party vendors may in turn subcontract or outsource some of their responsibilities to other parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive ~~information~~ **data** stored on those systems, make such systems ~~potentially~~ vulnerable to unintentional or malicious, internal and external attacks on our technology environment. **Furthermore, our ability to monitor the aforementioned third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.** In addition, **supply** ~~following the onset of the COVID - 19 pandemic~~ **chain attacks have increased in frequency and severity** , **and** we ~~enabled substantially all of~~ **cannot guarantee that third parties' infrastructure in our supply chain** ~~our -~~ **or** ~~employees to work remotely (and~~ **our third- party partners' supply chains have not been compromised. In addition, we** currently offer a hybrid- work environment ~~)~~ , which may make us more vulnerable to cyberattacks **as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program** . Potential vulnerabilities can be exploited from inadvertent or

intentional actions of our employees, third- party vendors, business partners, or by malicious third parties. ~~Attacks~~ **We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and / or software, including that** of ~~this nature~~ **third parties upon which we rely); however, we may not detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. Cyberattacks, malicious internet- based activity, online and offline fraud, and other similar activities** are increasing in their frequency, levels of persistence, sophistication and intensity, and are **also** being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, " hacktivists, " nation states and others. ~~In addition to the extraction of sensitive information, such~~ **Such** attacks could include the deployment of harmful malware **(including as a result of advanced persistent threat intrusions)** , ransomware **attacks** , denial- of- service attacks, **credential stuffing and / or harvesting,** social engineering **(including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of sensitive data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods** and other means to affect service reliability and threaten the confidentiality, integrity and availability of **our** information **systems and sensitive data** . ~~The~~ **In particular, severe ransomware attacks are becoming increasingly** prevalent ~~use of mobile~~ **and can lead to significant interruptions in our operations, ability to provide our products or** ~~devices~~ **services , loss** ~~further increases the risk~~ of **sensitive** data ~~security incidents~~ **and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments** . Significant disruptions of our, our third- party vendors' and / or business partners' information technology systems or other similar data security incidents could adversely affect our business operations and / or result in the loss, misappropriation and / or unauthorized access, use or disclosure of, or the prevention of access to, sensitive ~~information~~ **data** , which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. ~~There is no way~~ **We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry- standard or reasonable security measures to protect our information technology systems and sensitive data. Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors,** of ~~knowing~~ **security incidents. Such disclosures are costly, and the disclosure or the failure to comply** with ~~certainty whether~~ **such requirements could lead to adverse consequences. If** we **(or a third party upon whom we rely) experience a security incident or are perceived to** have experienced **a** ~~any data~~ security ~~incidents~~ **incident** ~~that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the ways that they conceal access to systems. Many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information~~ , including but not limited to **a security incident involving** personal information regarding employees or clinical trial patients, ~~could~~ **we may experience adverse consequences, such as** ~~disrupt~~ **disruptions to** our business, harm **to** our reputation, ~~compel us to comply with applicable federal~~ **government enforcement actions (for example, investigations, fines, penalties, audits, and inspections), additional reporting requirements** and / or **oversight** ~~state breach notification laws and foreign law equivalents~~ , **or we may otherwise be** subject ~~us to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us~~ to liability under laws, regulations **,** and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us and result in significant legal and financial exposure and / or reputational harm. Any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security- related legal or other obligations to third parties, or any further security incidents or other inappropriate access events resulting in the unauthorized access, release or transfer of sensitive **data** ~~information, which could include personally identifiable information~~ , may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us or we could be subject to claims by third parties that we have breached our privacy ~~,~~ or confidentiality- related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other inappropriate access can be difficult to detect ~~. Any~~ **and any** delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will ~~successfully prevent service interruptions~~ **be effective. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in** ~~or~~ **our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and** security **obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a security** ~~incidents~~ **incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details**

about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data of the Company or our customers could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel' s, or vendors' potential use of generative AI technologies. Social media platforms and AI- based platforms present new risks and challenges to our business. As social media continues to expand, it also presents us with new risks and challenges. Social media is increasingly being used to communicate information about us, our programs and the diseases our product candidates are being developed to treat. Social media practices in the biopharmaceutical industry are evolving, creating uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, a product or a product candidate, which could result in reporting obligations or other consequences . Further, ~~because of~~ the ~~work~~ **accidental or intentional disclosure of non** - **public information by our workforce or others through media channels could lead to information loss. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us, our products, or our product candidates on any social media platform. The nature of social media prevents us** from **having real** - ~~home policies we implemented due~~ **time control over postings about us on social media. We may not be able** to ~~COVID~~ **reverse damage to our reputation from negative publicity or adverse information posted on social media platforms or similar mediums. If any of these events were to occur or we otherwise fail to comply with application regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business including quick and irreversible damage to our reputation, brand image and goodwill. Additionally, AI** - ~~19, information that is normally protected~~ **based platforms are increasingly being used in the biopharmaceutical industry. The use of AI platforms by people** , including ~~company~~ **our vendors, suppliers and contractors, with access to our proprietary and** confidential information, **including trade** ~~may be less secure~~ - **secrets , may continue to increase and may lead to the release of such information, which may negatively impact our company, including our ability to realize the benefit of our intellectual property** . Risks Related to Our Financial Position and Capital Needs Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or be commercially viable. We are a clinical- stage biopharmaceutical company with limited operating history. We have no products approved for commercial sale and have not generated any product revenues to date, and we continue to incur significant research and development and other expenses related to our ongoing operations and clinical development of our product candidates. As a result, we are not and have never been profitable and have incurred losses in each period since our inception in 2005, except in 2021. For the year ended December 31, ~~2022~~ **2023** , we reported a net loss of $ ~~149~~ **209** . ~~3~~ **4** million. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~693~~ **902** . ~~0~~ **4** million, which included non- cash charges for stock- based compensation, preferred stock accretion and historical extinguishment charges. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our pre- commercialization activities for, and our research and development of, and seek regulatory approvals for, our product candidates. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of ~~future~~ growth of our expenses and our ability to generate revenues, if any. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our ability to generate product revenue and become profitable depends upon our ability to successfully commercialize our product candidates. We do not anticipate generating revenue from the sale of our product candidates for the foreseeable future. Our ability to generate future product revenue also depends on a number of additional factors, including, but not limited to, our ability to: • successfully complete the research and clinical development of, and receive regulatory approval for, our product candidates; • launch, commercialize and achieve market acceptance of our product candidates, and if launched independently, successfully establish a sales, marketing and distribution infrastructure; • continue to build a portfolio of product candidates through the acquisition or in- license of products, product candidates or technologies; • initiate preclinical and clinical trials for any additional product candidates that we may pursue in the future; • establish and maintain supplier and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply; • obtain coverage and adequate product reimbursement from third- party payors, including government payors; • establish, maintain, expand and protect our intellectual property rights; and • attract, hire and retain additional qualified personnel. In addition, because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of increased expenses, and if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide to or are required by the FDA or foreign regulatory authorities to perform studies or trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing our current product candidates and any other product candidates we may develop. Even if we generate revenues from the sale of our product candidates, we may not become profitable and may need to obtain additional funding to continue operations or acquire additional products that will require additional funding to develop them. If we fail to become profitable or do not sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations or even shut down. Our operations have consumed substantial amounts of cash since our inception, primarily due to our research and development efforts. We expect our research and development expenses to increase substantially in connection with our ongoing and planned activities. We believe that our existing cash, cash equivalents and short- term investments will fund our projected operating expenses and capital expenditure requirements for at least the next 12 months. Unexpected circumstances may cause us to consume capital more rapidly than we currently anticipate, including as a result of the global economic slowdown, including any recessions that have occurred or may occur in the future. In addition, we may discover that we need to conduct additional activities that exceed our

current budget to achieve appropriate rates of patient enrollment, which would increase our development costs. In any event, we will require additional capital to continue the development of, obtain regulatory approval for, and to commercialize our existing product candidates and any future product candidates. Any efforts to secure additional financing may divert our management from our day- to- day activities, which may adversely affect our ability to develop and commercialize our product candidates. While the long- term economic ~~impact~~ **impacts** ~~of either~~ **associated with public health crises and global geopolitical tensions, like** the **ongoing** ~~COVID- 19 pandemic or the~~ war between Russia and Ukraine ~~is~~ **and the war in Israel, are** difficult to assess or predict, each of these events has caused significant disruptions to the global financial markets and contributed to a general global economic slowdown. Furthermore, inflation rates have increased recently to levels not seen in decades. Increased inflation may result in increased operating costs (including labor costs) and may affect our operating budgets. In addition, the U. S. Federal Reserve has raised and is expected to further raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. If the disruptions and slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our financial condition and our ability to pursue our business strategy. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we do not raise additional capital when required or on acceptable terms, we may need to: • delay, scale back or discontinue the development or commercialization of our product candidates or cease operations altogether; • seek strategic alliances for our existing product candidates on terms less favorable than might otherwise be available; or • relinquish, or license on unfavorable terms, our rights to technologies or any future product candidates that we otherwise would seek to develop or commercialize ourselves. If we need to conduct additional fundraising activities and we do not raise additional capital in sufficient amounts or on terms acceptable to us, we may be unable to pursue development and commercialization efforts, which will harm our business, operating results and prospects. Our future funding requirements, both short- and long- term, will depend on many factors, including: • the initiation, progress, timing, costs and results of clinical trials of our product candidates; • the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more trials than we currently expect; • the cost to establish, maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights; • market acceptance of our product candidates; • the cost and timing of selecting, auditing and developing manufacturing capabilities, and potentially validating manufacturing sites for commercial- scale manufacturing; • the cost and timing for obtaining pricing, and coverage and reimbursement by third- party payors, which may require additional trials to address pharmacoeconomic benefit; • the cost of establishing sales, marketing and distribution capabilities for our product candidates if any candidate receives regulatory approval and we determine to commercialize it ourselves; • the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies; • the effect of competing technological and market developments; • our need to implement additional internal systems and infrastructure, including financial and reporting systems, as we grow our company; and • business interruptions resulting from geo- political actions, including war or the perception that hostilities may be imminent (such as the ongoing war between Russia and Ukraine **and the war in Israel**), terrorism, natural disasters, including earthquakes, typhoons, floods and fires, or public health crises. If we cannot expand our operations or otherwise capitalize on our business opportunities because we cannot secure sufficient capital, our business, financial condition and results of operations could be materially adversely affected. Changes in tax laws or regulations could materially adversely affect our company. New tax laws or regulations could be enacted at any time, and existing tax laws or regulations could be interpreted, modified or applied in a manner that is adverse to us, which could adversely affect our business and financial condition. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the Tax Act, enacted many significant changes to the U. S. tax laws, including changes in corporate tax rates, which collectively may impact the utilization of our NOLs and other deferred tax assets, the deductibility of expenses, and the taxation of foreign earnings. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, or any newly enacted federal tax legislation. Most recently, the IRA included a number of significant drug pricing reforms, including the establishment of a drug price negotiation program within the U. S. Department of Health and Human Services that would require pharmaceutical manufacturers to charge a negotiated **" "** maximum fair price **" "** for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation, and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs and Part D beneficiaries **'** annual out- of- pocket spending will be capped at $ 2, 000 beginning in 2025. The impact of changes under the Tax Act, the CARES Act, the IRA, or future reform legislation could increase our future U. S. tax expense and could have a material adverse impact on our business and financial condition. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred substantial losses during our history. We do not expect to become profitable in the near future, and we may never achieve profitability. Unused losses generally are available to be carried forward to offset future taxable income, if any. Under Sections 382 and 383 of the Code if a corporation undergoes an " ownership change, " generally defined as a greater than 50 % change (by value) in its equity ownership over a three- year period, the corporation' s ability to use its pre- change net operating loss carryforwards, or NOLs, and other pre- change tax attributes (such as research tax credits) to offset its post- change taxable income or taxes may be limited. We last completed an analysis **from January 1, 2021** through December 31, ~~2020~~ **2022** and **determined that no ownership changes had occurred in that period. Prior analyses**

determined that on March 30, 2007, August 21, 2015, and May 4, 2020, ownership changes had occurred. We may also experience ownership changes in the future as a result of shifts in our stock ownership, some of which may be outside of our control. As a result, our ability to use our pre- change NOLs to offset U. S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Risks Related to Intellectual Property **If we are unable to obtain or protect intellectual property rights in and to our product candidates, we may not be able to compete effectively in our market.** Our success depends in significant part on our and our licensors' and licensees' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed from third parties rights to patent portfolios. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we have licensed, and other licenses may not give us such rights. The patent prosecution process is expensive and time- consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors or licensees will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors or licensees fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' or licensees' patent rights are highly uncertain. Our and our licensors' or licensees' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors or licensees to narrow the scope of the claims of our or our licensors' or licensees' pending and future patent applications, which may limit the scope of patent protection that may be obtained. It is possible that third parties with products that are very similar to ours will circumvent our or our licensors' or licensees' patents by means of alternate designs or processes. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor' s technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidate, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidate or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products. Our and our licensors' or licensees' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours ~~. Entinostat composition of matter U. S. Patent RE39, 754, which we licensed from Bayer, covers the chemical entity of entinostat and any crystalline or non- crystalline form of entinostat and expired in September 2017. The portfolio we licensed from Bayer also includes U. S. Patent 7, 973, 166, or the ' 166 patent, which covers a crystalline polymorph of entinostat which is referred to as crystalline polymorph B, the crystalline polymorph used in the clinical development of entinostat. Many compounds can exist in different crystalline forms. A compound which in the solid state may exhibit multiple different crystalline forms is called polymorphic, and each crystalline form of the same chemical compound is termed a polymorph. A new crystalline form of a compound may arise, for example, due to a change in the chemical process or the introduction of an impurity. Such new crystalline forms may be patented. The ' 166 patent expires in 2029. On March 7, 2014, our licensor Bayer applied for reissue of the ' 166 patent. The reissue application seeks to add three inventors not originally listed on the ' 166 patent. The reissue application does not seek to amend the claims issued in the ' 166 patent. On April 28, 2015, the United States Patent and Trademark Office, or the USPTO, re- issued the ' 166 patent as U. S. patent RE45, 499. RE45, 499 reissued with the same claims originally issued in the ' 166 patent and the list of inventors on RE45, 499 now lists the additional three inventors that were not included on the ' 166 patent. The ' 166 patent has now been surrendered in favor of RE45, 499. RE45, 499 has the same term as the initial term of the ' 166 patent, which expires in August 2029. After expiry of RE39, 754, which occurred in September 2017, a competitor may develop a competing polymorphic form other than based on polymorph B, which**

~~could compete with polymorph B. In spite of our efforts and efforts of our licensor, we may not be successful in defending the validity of the claims of the RE45, 499 reissue patent or any of its foreign counterparts. If the claims of the ' 166 patent or any of its counterparts are found to be invalid by a competent court, we may not be able to effectively block entry of generic versions of our entinostat crystalline polymorph B candidate products into markets where the crystalline polymorph B patent claims are found to be invalid. Additionally, even if we submit an NDA before the expiration of U. S. Patent RE45, 499 and are successful in obtaining an extension of the term of U. S. Patent RE45, 499 based on FDA regulatory delays, such extension will only extend the term of RE45, 499 for a few additional years (up to a maximum of five additional years for patent claims covering a new chemical entity)~~ . The portfolio that we licensed from UCB includes granted patents and applications with pending claims directed to the composition of matter of axatilimab (a humanized, full- length IgG4 (kappa light chain) antibody with high affinity for the CSF- 1R) as well as claims directed to methods of use of axatilimab. There is no guarantee that any further patents will be granted based on the pending applications we licensed from UCB or even if one or more patents are granted that the claims issued in those patents would cover axatilimab, methods of using axatilimab, or formulations of axatilimab. Based on the priority date and filing date of the applications in the portfolio we licensed from UCB, we expect that additional patents, if any, granted based on the currently pending applications would expire in 2036. The actual term of any patents granted based on the pending applications we licensed from UCB can only be determined after such patents are ~~actually~~ granted. The portfolio that we licensed from Vitae Pharmaceuticals, which is now a subsidiary of AbbVie Inc., or AbbVie, includes granted patents and applications with pending claims directed to inhibitors of the interaction of menin with MLL and MLL fusion proteins, pharmaceutical compositions containing the same, and their use in the treatment of cancer and other diseases mediated by the menin- MLL interaction. There is no guarantee that any additional patents will be granted based on the pending applications that we licensed from AbbVie or even if one or more patents are granted that the claims issued in those patents would cover the desired lead compounds, compositions, and methods of use thereof. Based on the priority date and filing date of the applications in the portfolio that we licensed from AbbVie, we expect that a patent, if any, granted based on the currently pending applications would expire in 2037. The actual term of any patents granted based on the pending applications that we licensed from AbbVie can only be determined after such patents are ~~actually~~ granted. Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world is prohibitively expensive, and our or our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in countries outside the United States, or from selling or importing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our licensors to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our and our licensors' proprietary rights generally. Proceedings to enforce our and our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or interpreted narrowly and our and our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. In addition to India, certain countries in Europe and developing countries, including China, 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 and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. If we breach the UCB license agreement related to axatilimab or if the UCB license agreement is otherwise terminated, we could lose the ability to continue the development and commercialization of axatilimab. Our commercial success depends upon our ability to develop, manufacture, market and sell axatilimab. Subject to the achievement of certain milestone events, we may be required to pay UCB up to $ 119. 5 million in one- time development and regulatory milestone payments over the term of the UCB license agreement. If we or any of our affiliates or sublicensees commercializes axatilimab, we will also be obligated to pay UCB low double- digit royalties on sales, subject to reduction in certain circumstances, as well as up to an aggregate of $ 250 **. 0** million in potential one- time sales- based milestone payments based on achievement of certain annual sales thresholds. Under certain circumstances, we may be required to share a percentage of non- royalty income from sublicensees, subject to certain deductions, with UCB. Either party may terminate the UCB license

agreement in its entirety or with respect to certain countries in the event of an uncured material breach by the other party. Either party may terminate the UCB license agreement if voluntary or involuntary bankruptcy proceedings are instituted against the other party, if the other party makes an assignment for the benefit of creditors, or upon the occurrence of other specific events relating to the insolvency or dissolution of the other party. UCB may terminate the UCB license agreement if we seek to revoke or challenge the validity of any patent licensed to us by UCB under the UCB license agreement or if we procure or assist a third party to take any such action. Unless terminated earlier in accordance with its terms, the UCB license agreement will continue on a country- by- country and product- by- product basis until the later of: (i) the expiration of all of the licensed patent rights in such country; (ii) the expiration of all regulatory exclusivity applicable to the product in such country; and (iii) 10 years from the date of the first commercial sale of the product in such country. We cannot determine the date on which our royalty payment obligations to UCB would expire because no commercial sales of axatilimab have occurred and the last- to- expire relevant patent covering axatilimab in a given country may change in the future. If the UCB license agreement is terminated, we would not be able to develop, manufacture, market or sell axatilimab and would need to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all. In addition, our collaboration with Incyte to further develop and commercialize axatilimab is dependent upon the effectiveness of the UCB license agreement. If the UCB license agreement is terminated, Incyte may terminate our collaboration and our business could be adversely affected. If we breach the license agreement related to revumenib or if the license agreement is otherwise terminated, we could lose the ability to continue the development and commercialization of revumenib. Our commercial success depends upon our ability to develop, manufacture, market and sell revumenib. Subject to the achievement of certain milestone events, we may be required to pay Vitae, which is now a subsidiary of AbbVie, up to $ 99 **. 0** million in one- time development and regulatory milestone payments over the term of the AbbVie license agreement. In the event that we or any of our affiliates or sublicensees commercializes revumenib, we will also be obligated to pay AbbVie low single to low double- digit royalties on sales, subject to reduction in certain circumstances, as well as up to an aggregate of $ 70 **. 0** million in potential one- time sales- based milestone payments based on achievement of certain annual sales thresholds. Under certain circumstances, we may be required to share a percentage of non- royalty income from sublicensees, subject to certain deductions, with AbbVie. Either party may terminate the license agreement in its entirety or with respect to certain countries in the event of an uncured material breach by the other party. Either party may terminate the license agreement if voluntary or involuntary bankruptcy proceedings are instituted against the other party, if the other party makes an assignment for the benefit of creditors, or upon the occurrence of other specific events relating to the insolvency or dissolution of the other party. AbbVie may terminate the license agreement if we seek to revoke or challenge the validity of any patent licensed to us by AbbVie under the license agreement or if we procure or assist a third party to take any such action. Unless terminated earlier in accordance with its terms, the license agreement will continue on a country- by- country and product- by- product basis until the later of: (i) the expiration of all of the licensed patent rights in such country; (ii) the expiration of all regulatory exclusivity applicable to the product in such country; and (iii) 10 years from the date of the first commercial sale of the product in such country. We cannot determine the date on which our royalty payment obligations to AbbVie would expire because no commercial sales of revumenib have occurred and the last- to- expire relevant patent covering revumenib in a given country may change in the future. If the license agreement is terminated, we would not be able to develop, manufacture, market or sell revumenib and would need to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all. ~~If we breach our license agreement with Bayer related to entinostat or if the license agreement is otherwise terminated, we could lose the ability to continue the development and commercialization of entinostat. We have a license, development and commercialization agreement, or the Bayer license agreement, with Bayer pursuant to which we obtained a worldwide, exclusive license to develop and commercialize entinostat and any other products containing the same active ingredient. The Bayer license agreement, as amended, permits us to use entinostat or other licensed products under the Bayer license agreement for the treatment of any human disease, and we are obligated to use commercially reasonable efforts to develop, manufacture and commercialize licensed products for all commercially reasonable indications. We are obligated to pay Bayer up to approximately $ 50 million in the aggregate upon obtaining certain milestones in the development and marketing approval of entinostat, assuming that we pursue at least two different indications for entinostat or any other licensed product under the Bayer license agreement. We are also obligated to pay Bayer up to $ 100 million in aggregate sales milestones, and a tiered, single- digit royalty on net sales by us, our affiliates and sublicensees of entinostat and any other licensed products under the Bayer license agreement. We are obligated to pay Bayer these royalties on a country- by- country basis for the life of the relevant licensed patents covering such product or 15 years after the first commercial sale of such product in such country, whichever is longer. We cannot determine the date on which our royalty payment obligations to Bayer would expire because no commercial sales of entinostat have occurred and the last- to- expire relevant patent covering entinostat in a given country may change in the future. The Bayer license agreement will remain in effect until the expiration of our royalty obligations under the agreement in all countries. Either party may terminate the Bayer license agreement in its entirety or with respect to certain countries in the event of an uncured material breach by the other party. Either party may terminate the Bayer license agreement if voluntary or involuntary bankruptcy proceedings are instituted against the other party, if the other party makes an assignment for the benefit of creditors, or upon the occurrence of other specific events relating to the insolvency or dissolution of the other party. Bayer may terminate the Bayer license agreement if we seek to revoke or challenge the validity of any patent licensed to us by Bayer under the Bayer license agreement or if we procure or assist a third party to take any such action. If the Bayer license agreement is terminated, we would not be able to develop, manufacture, market or sell entinostat and would need to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all.~~ Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve

technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time- consuming, and inherently uncertain. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the ~~U. S. Patent and Trademark Office, or~~ USPTO, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future. In view of recent developments in U. S. patent laws, in spite of our efforts and the efforts of our licensors, we may face difficulties in obtaining allowance of our biomarker based patient selection patent claims or if we are successful in obtaining allowance of our biomarker based patient selection claims, we or our licensor may be unsuccessful in defending the validity of such claims if challenged before a competent court. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. On September 16, 2011, the Leahy- Smith America Invents Act, or the America Invents Act, was signed into law. The America Invents Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the ~~American~~ **America** Invents Act, and many of the substantive changes to patent law associated with the America Invents Act and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the America Invents Act will have on the operation of our business. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could harm our business and financial condition. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would harm our business. We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time- consuming and unsuccessful and have an adverse effect on the success of our business and on our stock price. Third parties may infringe our or our licensors' patents or misappropriate or otherwise violate our or our licensors' intellectual property rights. In the future, we or our licensors may initiate legal proceedings to enforce or defend our or our licensors' intellectual property rights, to protect our or our licensors' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensors to challenge the validity or scope of intellectual property rights we own or control. The proceedings can be expensive and time- consuming and many of our or our licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. Accordingly, despite our or our licensors' efforts, we or our licensors may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect our rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensors' patents at risk of being invalidated, held unenforceable or interpreted narrowly. Third- party pre- issuance submission of prior art to the USPTO, or opposition, derivation, reexamination, inter partes review or interference proceedings, or other pre- issuance or post- grant proceedings in the United States or other jurisdictions provoked by third parties or brought by us or our licensors or collaborators may be necessary to determine the priority of inventions with respect to our or our licensors' patents or patent applications. An unfavorable outcome could require us or our licensors to cease using the related technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors a license on commercially reasonable terms or at all. Even if we or our licensors obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors. In addition, if the breadth or strength of protection provided by our or our licensors' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this process. There could also be public announcements of the results of hearings, motions or

other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a downward effect on the price of shares of our common stock. Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have an adverse effect on the success of our business. Third parties may initiate legal proceedings against us or our licensors or collaborators alleging that we or our licensors or collaborators infringe their intellectual property rights or we or our licensors or collaborators may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, reexaminations, inter partes reviews or derivation proceedings before the United States or other jurisdictions. These proceedings can be expensive and time- consuming and many of our or our licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can. An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. 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. We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non- disclosure and non- competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. Litigation may be necessary to defend against these claims **.** In addition, for some of our in- licensed patents and patent applications, we do not have access to every patent assignments or employee agreements demonstrating that all inventors have assigned their rights to the inventions or related patents. As a result, we may be subject to claims of ownership by such inventors. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management. Our inability to protect our confidential information and trade secrets would harm our business and competitive position. In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, third- party manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Risks Related to Ownership of Our Common Stock and Other General Matters The trading price of our common stock is highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this **Annual** ~~report~~ **Report** , these factors include: • the success of competitive products or technologies; • regulatory actions with respect to our products or our competitors' products; • actual or anticipated changes in our growth rate relative to our competitors; • announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments; • results of trials of our product candidates or those of our competitors; • regulatory or legal developments in the United States and other countries; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • the level of expenses related to our product candidates or clinical development programs; • actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; • variations in our financial results or those of companies that are perceived to be similar to us; • fluctuations in the valuation of companies perceived by investors to be comparable to us; • share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; • announcement or expectation of additional financing efforts; • sales of our common stock by us, our insiders or our other stockholders; • changes in the structure of healthcare payment systems; • market conditions in the pharmaceutical and biotechnology sectors; and • general economic, industry, political and market conditions, including, but not limited to new or ongoing public health crises and the war between Russia and Ukraine **and the war in Israel** . In addition, the stock market in general, and the Nasdaq Global Select Market, or Nasdaq, and biopharmaceutical companies in particular, frequently experiences extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating

performance of such companies. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this " Risk Factors " section, could have a dramatic and negative impact on the market price of our common stock .-Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, **bank failures,** declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the COVID- 19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the **global** capital markets. Similarly, the current Russia- Ukraine war **exacerbated** ~~has created extreme~~ volatility in the global capital markets and **continues** ~~is expected~~ to ~~have further global economic consequences, including disruptions~~ ---- **disrupt** ~~of~~ the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Inflation can adversely affect us by increasing our costs, including personnel costs (wages). Any significant increases in inflation and related increase in interest rates could have a material adverse effect on our business, results of operations and financial condition **.** Until we can generate a sufficient amount of profit from our products, if ever, we expect to finance ~~our~~ future cash needs through public or private equity or debt offerings. If we raise additional funds through the issuance of additional equity or debt securities, it may result in dilution to our existing stockholders and / or increased fixed payment obligations ~~and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder~~ . For example, in December ~~2022~~ **2023** , we sold a total of ~~7~~ **12** , ~~840~~ **432** , ~~909~~ **431** shares of our common stock ~~and there were no~~ **in a public offering. The** ~~issuances~~ **issuance** of **these** ~~pre- funded warrants to purchase~~ shares of our common stock **resulted, and any future issuance pursuant to sales under the 2023 ATM Program will result, in dilution to our stockholders** . The shares of common stock into which the warrants may be exercised are considered outstanding for the purposes of computing earnings per share. Additionally, in ~~April~~ **November** ~~2022~~ **2023** , we sold ~~1~~ **2** , ~~111~~ **719** , ~~111~~ **744** common shares under the ~~2021~~ **2023** ATM Program, with net proceeds of approximately $ ~~19~~ **42** . ~~4~~ **1** million. The issuance of these shares of our common stock resulted, and any future issuance pursuant to the exercise of the outstanding pre- funded warrants or sales under the ~~2021~~ **2023** ATM Program will result, in dilution to our stockholders. We may also seek additional funding through government or other third- party funding and other collaborations, strategic alliances and licensing arrangements. These financing activities may have an adverse impact on our stockholders' rights as well as on our operations, and such additional funding may not be available on reasonable terms, if at all. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, if we seek funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. Any of these events could significantly harm our business, financial condition and prospects. If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If no or few securities or industry analysts continue coverage of us, the trading price for our stock could be negatively impacted. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our trials or operating results fail to meet the expectations of analysts, our stock price could decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence control over matters subject to stockholder approval. As of December 31, ~~2022~~ **2023** , our executive officers, directors, **and** holders of 5 % or more of our capital stock and their respective affiliates beneficially owned approximately ~~41~~ **37** . ~~9~~ **3** % of our outstanding voting stock and options. As a result, these stockholders will continue to have a significant influence over all matters requiring stockholder approval. For example, these stockholders may be able to influence 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 you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock. We may be subject to securities litigation, which is expensive and could divert management attention. The market price of our common stock may be volatile, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business. If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock. The Sarbanes- Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Commencing after the filing of our initial annual report on Form 10- K, we have been

required, under Section 404 of the Sarbanes- Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes- Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. We are required to get an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. Our compliance with Section 404 requires that we incur substantial expense and expend significant management efforts. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Global Select Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. Some provisions of our charter documents and Delaware law may have anti- takeover effects that could discourage an acquisition of us by others, even if an acquisition would benefit our stockholders and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15 % or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.