Risk Factors Comparison 2024-03-29 to 2023-03-28 Form: 10-K

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~~manufacturing, and controls data for our product candidates, could result in delays in regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we must comply with increasingly complex, rigorous, and sometimes conflicting laws, regulations, and standards enacted to protect business and personal data in the United States, Europe, and elsewhere. For example, the European Union has adopted the General Data Protection Regulation (the " GDPR "), the United Kingdom has adopted the Data Protection Act 2018 (as updated), and California has adopted the California Consumer Privacy Act (the " CCPA "). These laws impose additional obligations on companies regarding the handling of personal data and provide certain individual privacy rights to persons whose data is stored. Compliance with existing, proposed, and recently enacted laws, regulations, and standards (including implementation of the privacy and process enhancements called for under GDPR and CCPA) can be costly and time consuming, and any failure to comply with these laws, regulations, and standards could subject us to legal and reputational risks. Misuse of or failure to secure personal information, including any breach, loss, or compromise of clinical trial participant personal data, could also result in violation of data privacy laws, regulations, and standards against the Company by governmental entities or others, imposition of fines by governmental authorities, and damage to our reputation and credibility, and could have a negative impact on our business.~~ Risks Related to Our Financial Position and Need for Additional Capital We are at an early stage of development as a company **,** and our limited operating history may make it difficult to evaluate our ability to succeed. We were incorporated in ~~March~~ **December** ~~2019~~ **2018** , and our operations to date have been largely focused on licensing our product candidates, raising capital, building our management team and infrastructure **,** and conducting preclinical studies and early clinical trials. We have not yet demonstrated an ability to obtain regulatory approvals, manufacture products on a commercial scale ~~,~~ or partner with contract manufacturing organizations to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products. Moreover, we will need to eventually transition from a company with a development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications, and delays, and may not be successful in such a transition. We have incurred net losses since inception ~~,~~ and ~~we~~ expect to continue to incur significant net losses for the foreseeable future **, and there can be no assurance we will be able to raise capital** . We have incurred net losses in each reporting period since our inception, have not generated any revenue from product sales to date **,** and have financed our operations principally through the sale of our equity securities. Our losses have resulted principally from expenses incurred in connection with licensing our product candidates from Bayer, raising capital, building our management team and business infrastructure, **manufacturing,** and conducting preclinical studies and early clinical trials. As a result, we expect that it will be several years, if ever, before we have a commercialized product and are able to generate revenue from product sales. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our product candidates. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses as we discover, develop, and market additional potential products. The net losses we incur may fluctuate significantly from quarter to quarter such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, need to raise additional capital, and ability to achieve and maintain profitability. ~~52~~ We require substantial capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce, or eliminate one or more of our research and drug development programs or future commercialization efforts **and may not be able to continue as a going concern** . Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time- consuming, expensive, and uncertain process that takes years to complete. We expect our expenses to substantially increase in connection with our ongoing activities, particularly as we initiate and conduct clinical trials of, and seek marketing approval for, **VIP236, VIP943, VIP924,** enitociclib ~~, VIP236, VIP943, VIP924~~ , and our other product candidates. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. These expenditures will include payments associated with the Bayer License Agreement and development and commercial milestones, in each case prior to generating any product sales. Additionally, following commencement of any commercial sales of our licensed products, we will be responsible for significant further payments upon the achievement of certain sales milestones and tiered royalty payments on net commercial sales. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other **41** unanticipated costs may also arise. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing, and distribution. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. We also **expect to** incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing

operations. As of December 31, ~~2022~~ **2023**, we had approximately $ ~~52~~ **12**. ~~5~~ **8** million in cash ~~, and~~ **and** cash equivalents ~~, and marketable securities~~. We intend to use our existing capital resources to advance and expand our preclinical and clinical programs, to fund certain of the milestone payments under the Bayer License Agreement and our public company compliance costs, and for working capital and other general corporate purposes. Based on **our** current business plans and assumptions, we believe that our existing cash ~~, and~~ **and** cash equivalents ~~, and marketable securities~~ will be sufficient to fund our operating expenses and capital expenditure requirements into ~~late~~ **July** 2024. Our estimate as to how long we expect our existing cash to be able to continue to fund our operating expenses and capital expenditure requirements is based on plans and assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could result in less cash available to us or cause us to consume capital significantly faster than we currently anticipate, and we may need or choose to seek additional funds sooner than planned. We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements **,** or other sources, which may dilute our stockholders or restrict our operating activities. Raising additional funds by issuing equity or convertible debt securities may cause our stockholders to experience substantial dilution. Raising additional funds through debt financing may involve covenants that restrict our business activities and options. To the extent that we raise additional funds through collaborations and licensing arrangements, we may have to relinquish valuable rights to our drug discovery and other technologies, development programs, or product candidates, or grant licenses on terms that may not be favorable to us. Additional funding may not be available to us on favorable terms, or at all, particularly in light of the current economic and market conditions. We do not have any committed external source of funds. Market volatility resulting from ~~COVID- 19,~~ inflation and other economic and market conditions, the ~~war~~ **wars** in Ukraine **and Israel, the inability to maintain our listing on The Nasdaq Capital Market**, or other factors could also adversely impact our ability to access capital as and when needed. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend, or eliminate one or more of our preclinical programs, clinical trials, or future commercialization efforts **, or curtail our operations**. ~~53~~ **In accordance with Accounting Standards Update (" ASU ") 2014- 15, Disclosure of Uncertainties about an Entity' s Ability to Continue as a Going Concern (Subtopic 205- 40), we have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern for a period of one year after the date that our audited consolidated financial statements are issued. In light of our existing cash resources and current and expected operating losses and negative cash flows, we expect to need additional capital prior to the one- year anniversary of the issuance of our audited consolidated financial statements, and such additional capital may not be available as and when needed on acceptable terms or at all. As a result, we have concluded that these circumstances and the uncertainties associated with our ability to obtain additional capital raise substantial doubt about our ability to continue as a going concern for a period of one year after the date that our audited consolidated financial statements are issued. 42** The Bayer License Agreement obligates us to make significant milestone and royalty payments, some of which will be triggered prior to the commercialization of any of our other product candidates ~~. We will be responsible for significant future contingent payments and royalties under the Bayer License Agreement upon the achievement of certain development~~, ~~regulatory,~~ and ~~sales milestone events, some of which may occur prior to commercialization of any of our product candidates. In such event,~~ we ~~would~~ **may not** be ~~required to make certain of these payments prior to the time at which we are~~ able to **raise additional capital** ~~generate sufficient revenue, if any, from commercial sales of any of our product candidates. There can be no assurance that we will have the funds necessary to make such payments, be able to obtain the necessary funding on acceptable terms or at all,~~ or enter into strategic alliances at levels sufficient to pay these **amounts when due. We will be responsible for significant future contingent payments and royalties under the Bayer License Agreement upon the achievement of certain development, regulatory, and sales** ~~milestones~~ **milestone events, some of which may occur prior to commercialization of any of our product candidates. In such event, we would be required to make certain of these payments prior to the time at which we are able to generate sufficient revenue, if any, from commercial sales of any of our product candidates. Accordingly, we will need to obtain substantial additional funding or enter into strategic alliances in order to make these payments, and there can be no assurance that we will have the funds necessary to make such payments, be able to obtain the necessary funding on acceptable terms** or at all **, or enter into strategic alliances at levels sufficient to pay these amounts or at all**. If we are unable to ~~raise the necessary additional funding, enter into the necessary strategic alliances, or otherwise~~ pay these ~~milestones~~ **amounts**, we would be in breach of the Bayer License Agreement, which if not cured would give Bayer the right to terminate the agreement or seek other remedies, which would have a significant and adverse effect on our business and our ability to develop and commercialize our current product candidates, raise capital, or continue our operations **.** We may never achieve or sustain profitability. We do not know when or whether we will become profitable. To date, we have not commercialized any products or generated any revenues from the sale of products. We do not expect to generate any product revenues in the near term. To become and remain profitable, we must succeed in developing, obtaining regulatory approval for **,** and commercializing one or more of our product candidates. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, discovering and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, establishing commercialization capabilities for any approved products, and achieving market acceptance for any approved products. We may never succeed in these activities. Even if we succeed in these activities, we may never generate revenue in an amount sufficient to achieve **or sustain** profitability. Because of the numerous risks and uncertainties associated with biotechnology product development and commercialization, we are unable to accurately predict whether and when we will achieve profitability. If we are required by the FDA or any comparable regulatory authority in other jurisdictions to perform preclinical studies or clinical trials in addition to those we currently expect to conduct, or if there are any

delays or complications in completing preclinical studies of our product candidates or, if preclinical studies are successful, in submitting an IND application, a BLA or an NDA to the FDA, manufacturing clinical trial supplies, and completing clinical trials for our product candidates, our expenses could increase substantially and our ability to achieve profitability could be further delayed. ~~As we obtain certain developmental, regulatory, and sales milestones, we will be responsible for contingent milestone payments and royalties to Bayer under the Bayer License Agreement.~~ Even if we achieve profitability, we may not be able to sustain profitability in subsequent periods ~~. After we achieve profitability, if ever, we expect to continue to engage in substantial research and development activities and to incur substantial expenses to develop and commercialize additional product candidates. In addition, we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our revenues, expenses, and profitability. Our failure to achieve or sustain profitability would depress the market value of our common stock and could impair our ability to execute our business plan, raise capital, develop additional product candidates, or continue our operations~~ . Risks Related to Regulatory Approval and Other Legal Compliance Matters We may be unable to obtain U. S. or foreign regulatory approvals and, as a result, may be unable to commercialize our product candidates. Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, dose selection **and optimization** , efficacy, approval, recordkeeping, ~~54~~ reporting, labeling, storage, packaging, advertising, **and** promotion, pricing, marketing, and distribution. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain, and subject to **43** unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through **all** required ~~clinical~~ testing and obtain the regulatory approvals necessary for us to begin selling them. We have not conducted, managed, or completed large- scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority with respect to our product candidates. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity, and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can and often does change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, changes in policy, or new initiatives during the period of drug development, clinical trials, and FDA regulatory review. For example, in the U. S., the FDA' s Project Optimus initiative ~~will~~ **has** ~~transform~~ **transformed** the dose- finding and dose optimization paradigm across oncology to emphasize selection of a dose or doses that maximizes not only ~~the~~ efficacy of a drug but ~~the~~ **its** safety and tolerability as well, which could increase the development time and costs of our clinical trials. In addition, the European Union ~~began~~ **has** ~~transitioning~~ **transitioned** to full implementation of the EU Clinical Trials Regulation in January 2022, and the United Kingdom' s Medicines and Healthcare products Regulatory Agency ~~has begun to transition~~ **transitioned** the **United Kingdom** ~~U. K.~~ to a fully independent clinical trial regulatory framework ~~following Brexit~~ , both of which could result in significant uncertainties and delays. Any delay or failure in seeking or obtaining required approvals for a product candidate would have a material and adverse effect on our ability to generate revenue from such product candidate. Furthermore, any regulatory approval to market a product candidate may be subject to significant limitations on the approved uses or indications for which we may market ~~the~~ **such** product candidate or the labeling or other restrictions **of such product candidate** . In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy as part of approving an NDA or BLA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product candidate ~~. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe- use criteria and requiring treated patients to enroll in a registry~~ . These limitations and restrictions may significantly limit the size of the market for a product candidate and affect reimbursement by third- party payors. We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing **,** and third- party reimbursement. The foreign regulatory approval process varies among countries, and generally includes most if not all of the risks associated with FDA approval as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Any delay or failure in obtaining foreign regulatory approval for a product candidate would have a material and adverse effect on our ability to generate revenue from such product candidate in that foreign jurisdiction. Our current or future product candidates may cause adverse events, toxicities, or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential, or result in significant negative consequences. If our product candidates are associated with a high and unacceptable severity and prevalence of side effects or unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other ~~55~~ approved products or investigational new drugs, we may need to interrupt, delay, or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk- benefit perspective. Such results could result in a more restrictive label, implementation of a Risk Evaluation and Mitigation Strategy ~~,~~ or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Treatment- related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences could result in a more restrictive label or the delay or **44** denial of regulatory approval by the FDA or comparable foreign regulatory authorities and may prevent us from achieving or maintaining market acceptance of the affected product candidate, which could harm our business and prospects. Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not **previously** observed ~~in our preclinical studies~~

~~or previous clinical trials~~. Some of our product candidates may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, if ~~our~~ **such** product candidates are used in combination with other therapies, **they** ~~our product candidates~~ may exacerbate adverse events associated with the **other** therapy. Patients treated with our product candidates may also be undergoing surgical, radiation **,** and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to ~~the~~ **such** clinical trials, patients may drop out of our clinical trials, or we may be required to abandon the clinical trials or our development efforts of that product candidate altogether. We, the FDA, or other comparable regulatory authorities or an Institutional Review Board may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early- stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates that were not seen during clinical trials may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, implementation of a Risk Evaluation and Mitigation Strategy, significant restrictions on ~~the~~ use of the product, or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early- stage clinical trials. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of ~~our~~ **such** product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. **A** ~~For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing, promotion, and reimbursement of the product candidate in those jurisdictions. However, a~~ failure or delay in obtaining regulatory approval in one jurisdiction ~~56~~ may have a negative effect on the ~~regulatory~~ approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials **,** as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our products in certain jurisdictions. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced, and our ability to realize the full market potential of our product candidates ~~will~~ **would** be harmed. **45** Even if our product candidates receive regulatory approval, they will be subject to significant post- marketing regulatory requirements and oversight. Any regulatory approvals ~~that~~ we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of ~~the~~ **those** product ~~candidate~~ **candidates** , may contain significant limitations related to use restrictions ~~for specified age groups~~ , warnings, precautions, or contraindications, and may include burdensome post- approval ~~study~~ **studies** or risk management requirements. For example, the FDA may require a Risk Evaluation and Mitigation Strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans, or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information ~~and~~ **,** reports, **and** registration, ~~and~~ **as well as** on- going compliance with cGMP requirements and good clinical practices for any clinical trials that we conduct post- approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA 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 facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including: • delays in or the rejection of product approvals; • restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials; • restrictions on the products, manufacturers **,** or manufacturing ~~process~~ **processes** ; • warning or untitled letters; • civil and criminal penalties; • injunctions; • suspension or withdrawal of regulatory approvals; • ~~product~~ seizures, detentions, or import bans; • voluntary or mandatory ~~product~~ recalls and publicity requirements; • total or partial suspension of production; and • imposition of restrictions on operations, including costly new manufacturing requirements. ~~57~~ The occurrence of any event or penalty described above could inhibit our ability to commercialize our product candidates and generate revenue, require us to

expend significant time and resources in response, ~~and~~ generate negative publicity **, and harm our business and prospects** . ~~The~~ **There** ~~FDA' s and~~ **can be no assurance that we will be able to pursue accelerated or** other **expedited** ~~regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory~~ approval **of any** of our product candidates ~~. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies~~ , ~~or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained,~~ and ~~we may not achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislative, administrative, or executive action, either in the United States or abroad. Such actions could impact our business and industry, including by imposing significant burdens on, or otherwise materially delaying, the FDA' s and other~~ -- **the failure** ~~regulatory authorities' ability to engage in regulatory and oversight activities. If these actions impose constraints on the ability of the FDA or other regulatory authorities to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through accelerated approval pathways. If we are unable~~ to obtain such **accelerated or other expedited** approval ~~, we may be required~~ **would result in a longer time period** to **commercialization of such product candidates** ~~conduct additional preclinical studies or clinical trials beyond those that we anticipated~~ , which could increase the ~~expense~~ **cost** of **development** ~~obtaining,~~ and **harm** ~~delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or~~ **our competitive position in** ~~if we do not comply with rigorous post- marketing requirements,~~ the **marketplace** ~~FDA may seek to withdraw accelerated approval~~ . We may choose to seek an accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant ~~accelerated~~ **expedited** approval to a product candidate designed to treat a **46** serious or life- threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that ~~the~~ **such** product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor' s agreement to conduct, in a diligent manner, additional post- approval confirmatory studies to verify and describe the drug' s clinical benefit. If such post- approval studies fail to confirm the drug' s clinical benefit, the FDA may withdraw its approval of the drug. ~~Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and otherwise evaluate our ability to seek and receive accelerated approval.~~ There can be no assurance that ~~after our evaluation of the feedback and other factors~~ we will decide to pursue **,** ~~or submit an NDA or BLA for~~ **or subsequent to FDA feedback continue to pursue,** accelerated approval or any other form of expedited development, review, or approval. **Furthermore** ~~Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review, or approval~~ , even ~~if we initially decide to do so. Furthermore,~~ if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e. g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application ~~will~~ **would** be accepted or that any expedited development, review, or approval ~~will~~ **would** be granted on a timely basis ~~,~~ or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review, or approval for our product candidates would result in a longer time period to commercialization of such product candidates, could increase the cost of development of such product candidates, and could harm our competitive position in the marketplace. ~~58 The FDA, European Medicines Agency, and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction. We may also conduct international clinical trials. The acceptance of study data by the FDA, European Medicines Agency, or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign- generated data alone unless (1) the data are applicable to the United States population and United States medical practice, (2) the clinical trials are performed by clinical investigators of recognized competence and pursuant to current good clinical practice requirements, and (3) the FDA is able to validate the data through an on- site inspection or other appropriate mean. Additionally, the FDA' s clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. Such foreign clinical trials would also be subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted. There can be no assurance that the FDA, European Medicines Agency, or any applicable foreign regulatory authority will accept data from clinical trials conducted outside of its applicable jurisdiction. If the FDA, European Medicines Agency, or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional clinical trials, which would be costly, time- consuming, and delay aspects of our business plan and may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction. The United Kingdom' s withdrawal from the European Union imposes new regulatory costs and challenges that may have a negative effect on our business. The United Kingdom left the European Union on January 31, 2020, an event commonly referred to as " Brexit, " and following the " transition period, " on December 30, 2020, the European Union, the European Atomic Energy Community, and the United Kingdom signed a Trade and Cooperation Agreement. Brexit imposes new regulatory costs and challenges that may have a material adverse effect on us and our operations. We may face decreased chances to obtain market approval for our products in the European Union, including the possibility that the European Medicines Agency will not accept data from our clinical trials conducted in the United Kingdom or will only do so if we comply with certain conditions. Conversely, since a significant proportion of the~~

~~United Kingdom' s regulatory framework affecting the pharmaceutical and biotechnological industry is derived from European Union directives and regulations, Brexit could materially alter the regulatory regime with respect to our product candidates in the United Kingdom, which may increase the time and costs associated with obtaining regulatory approval from the relevant authorities. It may also be time- consuming and expensive for us to alter our internal operations in order to comply with new regulations. Altered regulations could also add time and expense to the process by which our product candidates receive regulatory approval in the United Kingdom and the European Union. In addition, following the Brexit vote, the European Union moved the European Medicines Agency' s headquarters from the United Kingdom to the Netherlands. This transition may cause disruption in the administrative and medical scientific links between the European Medicines Agency and the UK Medicines and Healthcare products Regulatory Agency, including delays in granting clinical trial authorization or marketing authorization, disruption of import and export of active substance and other components of new drug formulations and disruption of the supply chain for clinical trial product and final authorized formulations. The United Kingdom' s Medicines and Healthcare products Regulatory Agency has also begun to transition the U. K. to a fully independent clinical trial regulatory framework. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the European Union and / or the United Kingdom. 59~~ We may be required to defend lawsuits or pay damages in connection with the alleged or actual violation of healthcare statutes such as fraud and abuse laws, and our corporate compliance programs **cannot** ~~can never~~ guarantee that we ~~are~~ **will** always **be** in compliance with all relevant laws and regulations. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws, commonly referred to as " fraud and abuse " laws, have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. Other jurisdictions, such as Europe, have similar laws. These laws include false claims and anti- kickback statutes. Anti- kickback laws make it illegal for a manufacturer to offer or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase of a product. ~~The U. S. government has published many regulations relating to the anti- kickback statutes, including numerous safe harbors or exemptions for certain arrangements.~~ False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third- party payors **,** including Medicare and Medicaid, claims for reimbursed products or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products will be subject to scrutiny under these laws and regulations. It may be difficult to determine whether or not our activities comply with these complex legal requirements **, and our corporate compliance programs cannot guarantee that we will always be in compliance with all relevant laws and regulations** . Violations are punishable by significant criminal and ~~/ or~~ civil fines and other penalties, as well as the possibility of exclusion of the **affected** product from coverage under governmental healthcare programs, including Medicare and Medicaid. If U. S. or foreign governments were to investigate or make allegations against us or any of our employees, or sanction or convict us or any of our employees, for violations of any of these legal requirements, this could have a material adverse effect on our business ~~, including our stock price. Our activities could be subject to challenge for many reasons, including the broad scope~~ and **prospects** ~~complexity of these laws and regulations, the difficulties in interpreting and applying these legal requirements, and the high degree of prosecutorial resources and attention being devoted to the biopharmaceutical industry and healthcare fraud by law enforcement authorities. During the last few years, numerous biopharmaceutical companies have paid multi- million dollar fines and entered into burdensome settlement agreements for alleged violation of these requirements, and other companies are under active investigation. Although we have developed and implemented corporate and field compliance programs, we cannot assure you that we or our employees, directors, or agents were, are, or will be in compliance with all laws and regulations or that we will not come under investigation, allegation, or sanction. In addition, we may be required to prepare and report product pricing- related information to federal and state governmental authorities, such as the Department of Veterans Affairs and under the Medicaid program. The calculations used to generate the pricing- related information are complex and require the exercise of judgment. If we fail to accurately and timely report product pricing- related information or to comply with any of these or any other laws or regulations, various negative consequences could result, including criminal and / or civil prosecution, substantial criminal and / or civil penalties, exclusion of the approved product from coverage under governmental healthcare programs including Medicare and Medicaid, costly litigation, and restatement of our financial statements. In addition, our efforts to comply with this wide range of laws and regulations are, and will continue to be, time- consuming and expensive~~ . Our employees, agents, contractors, or collaborators may engage in misconduct or other improper activities. We cannot ensure that our **corporate** compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators, including ~~, but not limited to,~~ contract research organizations, electronic data capture companies, data management companies, contract clinical **47** research associates, medical institutions, clinical investigators, contract laboratories, and other third parties ~~to assist us in conducting clinical trials and obtaining regulatory approvals for our product candidates~~ , that would violate the laws or regulations of the jurisdictions in which we operate, including ~~, without limitation,~~ healthcare, employment, foreign corrupt practices, environmental, competition, and ~~patient and other~~ privacy laws and ~~60~~ regulations ~~. Misconduct by these parties could include intentional failures to comply with FDA or other applicable regulations, provide accurate information to the FDA and comparable regulatory authorities in other jurisdictions, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. Such misconduct also could involve the improper use of information obtained from clinical trials or interactions with the FDA or comparable regulatory authorities in other jurisdictions. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase~~ . Such improper actions could subject us to civil or criminal investigations, and **civil** ~~monetary and injunctive~~ penalties, and could adversely impact our business and ~~reputation~~ **prospects** . ~~In addition~~ **For example** , we are subject to the

Foreign Corrupt Practices Act and similar anti- bribery or anti- corruption laws, regulations, ~~or~~ **and** rules of other countries in which we operate. The Foreign Corrupt Practices Act generally prohibits offering, promising, giving, or authorizing others to give **,** anything of value, either directly or indirectly, to a non- U. S. government official in order to influence official action ~~,~~ or otherwise obtain or retain business. The Foreign Corrupt Practices Act also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non- U. S. governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities ~~;~~ ~~therefore~~ , **and** our dealings with these prescribers and purchasers are **therefore** subject to regulation under the Foreign Corrupt Practices Act. There is no certainty that our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. While we have implemented codes of conduct and other policies and controls to mitigate the risk of non- compliance with anti- corruption and anti- bribery laws, it is not always possible to identify and deter employee misconduct, 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 government investigations or other actions stemming from a failure to comply with these laws or regulations. Violations of ~~these~~ **such** laws and regulations could result in, among other things, administrative, civil ~~,~~ and criminal fines and sanctions against us, our **directors,** officers, or ~~our~~ employees, the closing ~~down~~ of our facilities, requirements to obtain export licenses, exclusion from participation in federal healthcare programs including Medicare and Medicaid, implementation of compliance programs, integrity oversight and reporting obligations, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our business ~~, reputation, brand~~ -- **and prospects** ~~, international expansion efforts, and ability to attract and retain employees~~ . Risks Related to Our Dependence on Third Parties Our applications for regulatory approval could be delayed..... for our product candidates. 61 Our manufacturing processes are complex, and we **do not currently** have ~~no~~ **our own** manufacturing ~~capability~~ **capabilities** and will initially rely on third- party manufacturers for the development, clinical trials, and commercialization of any product candidate we may develop or sell. The processes for manufacturing our product candidates, particularly our bioconjugation ~~product~~ candidates, are very complex and take significant time and resources to develop and implement. In addition, our supply chain of raw materials, consumables, intermediates, drug substances, and drug products for use in our clinical trials and, if approved by regulatory authorities, commercialization rely on a worldwide supply chain. We do not currently operate our own manufacturing facilities or have our own manufacturing capabilities for clinical or commercial production of our product candidates under development and intend to initially rely on third- party ~~manufactures~~ **manufacturers** ~~for any such manufacturing~~ . Third- party manufacturers that have the capabilities, processes, and expertise that we need for our product candidates and that can meet our quality standards may be difficult to identify or retain, and even if retained, such third- party manufacturers may not be able to perform the manufacturing services we require within our planned timeframes. We anticipate relying on a limited number of third- party manufacturers until such time, if any, as we decide to expand our operations to include manufacturing capabilities. **Certain of our key third- party manufacturers are located in China, and the United States and China are currently experiencing geopolitical tensions that could result in legislation or government intervention that adversely impacts our ability to manufacture in China, which could necessitate transitioning such manufacturing to other third- party manufacturers and increase costs, delay manufacturing, and lengthen timelines. In addition, the European Union, 48 which is experiencing, and could continue to experience, the impact of the wars in Ukraine and Israel on supply chains, and other economic matters, including inflation. Such third- party manufacturers may implement, and certain of such manufacturers have implemented, price increases that could negatively impact our ability to afford their services.** If the FDA or comparable foreign regulatory authorities approve any of our product candidates for commercial sale, or if we significantly expand our clinical trials, we will need to manufacture them in larger quantities, and we may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or economic manner ~~,~~ or at all. Until such time, if any, that we directly control the manufacturing of our product candidates, we will have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance, and qualified personnel, and we will be dependent on our third- party manufacturing partners for compliance with current cGMP requirements for the manufacture of our product candidates. If our third- party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we ~~will~~ **may** not be able to secure or maintain regulatory approval for our product candidates. In addition, if any third- party manufacturer makes improvements in the manufacturing process for our product candidates, we may not own, or may have to share, the intellectual property rights to such ~~innovations. Certain of our key third- party manufacturers are located in the European Union, which is now experiencing the direct impact of the war in Ukraine on supply chains and other economic matters, including inflation. Such third- party manufacturers may implement~~ **improvements** ~~, and certain of such manufacturers have begun to implement, price increases that could negatively impact our ability to afford such manufacturing services~~ . Any inability to identify and retain third- party manufacturers on a cost- effective basis, **any** performance failure on the part of such manufacturers, or **any** disruption in our supply chain as a result of **economic uncertainty,** political unrest, **the wars in Ukraine and Israel,** trade disputes, natural disasters, pandemics or epidemics, climate change, or otherwise, could delay ~~our~~ **the development,** clinical trials ~~and development~~ , regulatory approval **, or commercialization** of our product candidates, **which would harm** ~~commercialization of our product candidates, or~~ **our business** ~~our ability to sell our commercial products, resulting in additional losses~~ and **prospects** ~~depriving us of potential product revenues~~ . If we fail to enter into and maintain successful collaborative arrangements or strategic alliances for our product candidates, we may have to reduce or delay our product candidate development or increase our expenditures. An

important element of our strategy for developing, manufacturing, and commercializing our product candidates is entering into collaborative arrangements or strategic alliances with pharmaceutical companies, research institutions, or other industry participants to advance our programs and enable us to maintain our financial and operational capacity. We face significant competition in seeking ~~appropriate~~ **such** collaborations and alliances. We may not be able to negotiate such collaborations or alliances on acceptable terms ~~,~~ if at all. In addition, such collaborations or alliances may be unsuccessful. If we fail to create and maintain suitable collaborations or alliances, we may have to limit the size or scope of, or delay, one or more of our research or ~~62~~ development programs. In addition, these kinds of collaborative arrangements and strategic alliances may place certain aspects of the development of our product candidates outside of our control, ~~may~~ require us to relinquish important rights, **limit ~~or~~ our ~~may~~ commercial opportunities, or** otherwise be on terms unfavorable to us. Dependence on collaborative arrangements or strategic alliances will subject us to several risks, including the ~~risk~~ **risks** that: • we may not be able to control the amount and timing of resources that our collaborators may devote to ~~the~~ **our** product candidates; • our collaborators may experience financial difficulties; • we may be required to relinquish important rights such as marketing and distribution rights; • business combinations or significant changes in a collaborator' s business strategy may adversely affect **its ~~a collaborator' s~~** willingness or ability to complete its obligations under any arrangement; • a collaborator could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and • collaborative arrangements are often terminated or allowed to expire, which would delay development and may increase the cost of developing our product candidates. **49** Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates proceed through preclinical and clinical trials towards potential approval and commercialization, various aspects of the development program, such as manufacturing methods and formulation, may be altered along the way to optimize processes and results or due to other factors. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our current or future product candidates to perform differently and affect the costs, results, or timing of planned preclinical or clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification **,** or FDA approval. This could delay completion of preclinical studies or clinical trials, require the conduct of bridging clinical trials, or ~~the~~ repetition of one or more clinical trials, increase clinical trial costs, delay approval of product candidates, or jeopardize our ability to commence sales and generate revenue **.Our** applications for regulatory approval could be delayed or denied due to problems with studies conducted before we in- licensed the rights to some of our product candidates.We currently license all of our product candidates from Bayer pursuant to the Bayer License Agreement.Our present development involving these product candidates relies to a ~~significant~~ **certain** extent upon previous development conducted by Bayer or other third parties over whom we had no control and before we in- licensed ~~the~~ **such** product candidates.To receive regulatory approval of a product candidate,we must present all relevant data and information obtained during its development,including research conducted prior to our licensure of ~~the~~ **such** product candidate.Although we are not currently aware of any such problems,any problems that emerge with preclinical or clinical development conducted prior to our in- licensing may affect future results or our ability to document prior development and ~~to~~ conduct clinical trials,which could delay,limit **,** or prevent regulatory approval for our product candidates ~~.61~~ . Due to our intention to rely in part on contract research organizations and other third parties to conduct clinical trials, we may be unable to directly control the timing, conduct, and expense of all aspects of our clinical trials. We intend to rely in part on contract research organizations, electronic data capture companies, data management companies, contract clinical research associates, medical institutions, clinical investigators, contract laboratories, and other third parties to assist us in conducting clinical trials and obtaining regulatory approvals for our product candidates. In addition, we intend to rely in part on third parties to assist with our preclinical development of **such** product candidates. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, need to be replaced, or the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols ~~,~~ **or** regulatory requirements ~~,~~ or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended, or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. ~~63~~ Risks Related to Our Intellectual Property If we fail to comply with our obligations under any license, collaboration, or other agreement, including the Bayer License Agreement, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates. Pursuant to the Bayer License Agreement, we have been granted a license from Bayer to certain intellectual property rights covering **VIP236, VIP943, VIP924,** enitociclib ~~, VIP236, VIP943, VIP924~~ , and our other product candidates. If, for any reason, our licenses under the Bayer License Agreement are terminated or we otherwise lose those rights, our business will be significantly and adversely affected. The Bayer License Agreement imposes, and any future collaboration agreements or license agreements we may choose to enter are likely to impose, various **50** development, commercialization, funding, milestone payment, royalty, diligence, sublicensing, patent prosecution and enforcement, or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages, and Bayer and any other licensor **,** may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell products that are covered by the licensed technology ~~,~~ or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology. Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which our product candidates, technology, and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • the sublicensing of patent and other rights under our third- party relationships; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by us, our licensors, and our partners; and • the priority of invention of patented technology. In addition, the Bayer License Agreement under which we license our

core intellectual property and technology is complex, and certain provisions in the agreement may be susceptible to multiple interpretations. The resolution of any disagreement that may arise as a matter of contract interpretation could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under that agreement, either of which could have a material adverse effect on our business **and prospects** . Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate, which could have a material adverse effect on our business and prospects. Our success depends on our ability to protect our intellectual property and our proprietary technologies. Our commercial success depends in part on our ability to obtain and maintain **intellectual property** ~~patent protection and trade secret protection~~ for **VIP236, VIP943, VIP924,** enitociclib ~~, VIP236, VIP943, VIP924~~ , and our other product candidates, proprietary technologies, and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the U. S. and abroad related to our product candidates, ~~proprietary~~ technologies, and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in- licensing relevant issued patents or pending applications from third parties. ~~64~~ Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or the patent applications of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our and our licensors' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and / or **51** limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our **business** ~~financial condition~~ and **prospects** ~~results of operations~~ . Although we ~~will~~ have licensed **issued** patents that cover ~~enitociclib under the Bayer License Agreement~~ **certain of our product candidates and technologies** , we do not have issued patents covering **all** our ~~other~~ product candidates **and technologies** , and we may need additional issued patents covering ~~enitociclib~~ **such product candidates and technologies** . We cannot be certain that the claims in **any of** our ~~other~~ U. S. pending patent applications, corresponding international patent applications ~~, and patent applications in certain foreign territories~~ , or those of our licensors, will be considered patentable by the USPTO, courts in the U. S., or the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patents or our licensor' s issued patents will not be found invalid or unenforceable if challenged. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following: • the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction; • patent applications may not result in any patents being issued; • patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage; • our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek, or may have already obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential product candidates; • there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the U. S. for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and • countries other than the U. S. may have patent laws less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates. The patent prosecution process is also expensive and time- consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. ~~65~~ In addition, although we enter ~~into~~ non- disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, contract research organizations, third- party manufacturers, consultants, advisors, and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to ~~seek and~~ obtain patent protection. 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 intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. **52** If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected. The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability **,** and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates. ~~Moreover~~ **In addition** , the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in- license currently or

in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in- license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of our licensors by developing similar or alternative technologies or products in a non- infringing manner which could materially adversely affect our business and prospects. ~~ours even if we had made the invention before it was made by such third party.This will require us to be cognizant going forward of the time from invention to filing of a patent application.~~ Furthermore,our ability to obtain and maintain valid and enforceable patents **also** depends on whether the differences between our technology and the prior art allow our technology to be ~~68~~ patentable over the prior art.Since patent applications in the United States and most other countries are confidential for a period ~~of time~~ after filing ~~or until issuance~~ ,we may not be certain that we or our licensors are the first to ~~either~~ file any patent application related to our **drug** product candidates or ~~invent any~~ **technologies,potentially having a material adverse effect on our business and prospects.This will require us to be to be aware** of the ~~inventions claimed~~ **possibility of adverse determinations** in **any such submissions or proceedings,potentially reducing** the ~~patents~~ **scope** or **enforceability of,or invalidate,our** patent ~~applications~~ **rights,which would adversely affect our competitive position** . ~~The Leahy-~~ The issuance of a patent is not conclusive as to its inventorship, scope, validity ~~,~~ or enforceability, and our patents or the patents of our licensors may be challenged in the courts or patent offices in the U. S. and abroad. We may be subject to a third- party pre- issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post- grant review and inter partes review, or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates **,** and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Moreover, our patents or the patents of our licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our licensors. Such challenges may result in loss of patent rights, loss of exclusivity, or **in** patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates. ~~66~~ **53** The validity, scope, and enforceability of any patents that cover a biologic subject to approval by the FDA via a BLA, such as VIP943 and VIP924, can be challenged by third parties. For biologics subject to approval by the FDA via a BLA, such as VIP943 and VIP924, the BPCIA provides a mechanism for one or more third parties to seek FDA approval to manufacture or sell biosimilar or interchangeable versions of brand name biological products. If a biosimilar applicant successfully challenges our asserted patent claims, it could result in the invalidation of, or render unenforceable, some or all our relevant patent claims or result in a finding of non- infringement. Such litigation or other proceedings to enforce or defend our intellectual property rights are complex in nature, may be very expensive and time-consuming, may divert our management' s attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with VIP943 and VIP924 or any future biological product candidates. We may be involved in lawsuits to protect or enforce our patents or our licensors' patents, which could be expensive, time consuming, and unsuccessful. Further, our issued patents or our licensors' patents could be found invalid or unenforceable if challenged in court. Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in- license is not valid, is unenforceable, or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patents or the patents of our licensors are invalid or unenforceable in whole or in part. ~~In patent litigation in the U. S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non- enablement, or obviousness- type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.~~ Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation, and prior art could render our patents or our licensors' patents invalid. Such mechanisms include re- examination, post- grant review, inter partes review, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of ~~,~~ or amendment to our patents or our licensors' patents in such a way that they no longer cover our ~~technology~~ **current** or **future** ~~platform, or any~~ product candidates ~~that we may develop~~ **, technologies, or VersAptx platform** . The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we

would lose at least part, and perhaps all, of the patent protection on our ~~technology~~ **current** or **future** ~~platform, or any~~ product candidates ~~that we may develop~~ **, technologies, or VersAptx platform** . In addition, if the breadth or strength of protection provided by our patents and patent applications or the patent and patent applications of our licensors is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business and prospects. Moreover, the issuance of a patent does not necessarily give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented ~~product~~ **products** and practicing our own patented ~~technology~~ **technologies** . ~~67~~ Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings **54** adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common stock to decline. During any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs, or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business and prospects. Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party. Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using **relevant inventions** ~~the related technology~~ or to attempt to license rights ~~to it~~ from the prevailing party. Our business could be harmed if the prevailing party ~~does~~ **would** not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue ~~our~~ clinical trials ~~, continue our~~ **or** research programs, license necessary technology from third parties, or enter into development or manufacturing partnerships that would help us bring our product candidates to market. Patent reform legislation could increase the uncertainties..... material adverse effect on our business. Changes in U. S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property, increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents and weaken our ability to obtain new patents or to enforce our existing patents and the patents we might obtain or license in the future. We may be subject to claims challenging the inventorship or ownership of our licensor' s patents, our patents ~~,~~ and other intellectual property. We may also be subject to claims that former employees or other third parties have an ownership interest in our licensor' s patents, our patents, or other intellectual property. Litigation **or other proceedings** may be necessary to defend against these and other claims challenging inventorship or ownership. **For example, because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.** If we fail in defending any such claims, in **55** addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business **and prospects** . Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees. Patent terms may **not** ~~be inadequate to~~ protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. ~~non-provisional~~ filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from ~~competitive~~ products **of third parties** . 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 ~~69~~ are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not obtain patent term extension for our product candidates, our business may be materially harmed. Depending upon the timing, duration ~~,~~ and specifics of FDA marketing approval of our product candidates, one or more of our patents or in- licensed patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984. **This** ~~The Drug Price Competition and Patent Term Restoration~~ Act ~~of 1984~~ permits a patent restoration term of up to five years as compensation for patent term lost during product development and ~~the~~ FDA regulatory review ~~process~~ . A maximum of one patent may be extended per FDA approved product

as compensation for the patent term lost during ~~the~~ FDA regulatory review ~~process~~ . A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only those claims covering such approved drug product, a method for using it, or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data ~~and~~ **to** launch their product earlier than might otherwise be the case. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, and defending patents in all countries throughout the world ~~would~~ **can** be prohibitively expensive, and our 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 the ~~federal and state~~ laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our product candidates, and our patents, the patents of our licensors, or other intellectual property rights may not be effective or sufficient to prevent them from competing. **The requirements for patentability differ regionally. Some countries limit the enforceability of patents against government agencies or government contractors, while others have compulsory licensing laws under 56 which a patent owner may be compelled to grant licenses to third parties. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and prospects may be adversely affected. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies and product candidates. While we will endeavor protect our technologies and product candidates with intellectual property rights such as patents, the process of obtaining patents is time consuming, expensive, and unpredictable.** Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of **some** ~~many foreign~~ countries do not favor ~~the~~ **patent** enforcement ~~of patents~~ and other intellectual property protection, which could make it difficult for us to stop ~~the~~ infringement of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights **. Beginning in March 2023, European patent applicants have the option of participating in the Unitary Patent System (" UPS "), subject to the jurisdiction of the Unitary Patent Court (" UPC "), on an issued patent- by- issued patent, or patent application- by- patent application basis. This new system is a significant change in European patent practice, and the UPC is a new court system, with no established legal precedent, resulting in uncertainty for patent holders and applicants. We will consider, case- by- case, with each individual patent or application, the risks and benefits of participating in the UPS. We will continue to monitor the evolution of the UPS and UPC, especially over the course of its seven- years' transitional period as the new system and the new court gains footing** . Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of not issuing or being invalidated or interpreted narrowly ~~,~~ and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution, maintenance, or enforcement of our patent applications or issued patents or those of ~~70~~ any current or future licensors. For example, United States and foreign government actions related to Russia' s invasion of Ukraine have limited and prevented the filing, prosecution, and maintenance of patent applications and issued patents in Russia, and actions by the Russian government allow Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. These actions could adversely affect our business ~~. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business may be adversely affected~~ . Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment, and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and applications will be due to the USPTO and various foreign patent offices at ~~various~~ **many** points over the lifetime of our licensor' s patents and applications and those that we own. We rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with many procedural, documentary, fee payment, and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the ~~particular~~

relevant jurisdiction. However, 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. If such an event were to occur, it could have a material adverse effect on our business **and prospects** . **57** If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected. We intend to use registered and unregistered trademarks or trade names to brand and market ourselves and our products **and technologies** . Our trademarks or trade names may be challenged, infringed, circumvented ~~,~~ or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential **business** partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks like ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Our efforts to enforce or protect our proprietary rights related to trademarks and trade names may be ineffective and could result in substantial costs and diversion of resources. If we are unable to enforce and protect our trademarks and tradenames and establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business **and prospects** could be adversely affected. If we are unable to protect the confidentiality of our ~~trade secrets~~ **proprietary information** , our business and competitive position would be harmed. We rely on the protection of our ~~trade secrets~~ **proprietary information** , including ~~unpatented~~ **our technologies and** know- how, ~~technology, and other proprietary information~~ to maintain our competitive position. Although we have taken steps to protect **such information** ~~our trade secrets and unpatented know- how~~ , including entering ~~into~~ confidentiality agreements with third parties and confidential information and inventions agreements with employees, consultants, and advisors, we cannot provide any assurances that ~~all~~ **these parties would not breach** such agreements ~~have been duly executed, and any of these parties may breach 71 the agreements~~ and disclose our proprietary information ~~, including our trade secrets~~ , and we may not be able to obtain adequate remedies ~~for~~ **in the event of** such breaches. Enforcing ~~a claim~~ **claims** that a party illegally **used or** disclosed **such information** ~~or misappropriated a trade secret~~ is difficult, expensive, and time- consuming, and the outcome is unpredictable. ~~In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.~~ Moreover, third parties may ~~still~~ obtain ~~this information~~ or ~~may~~ come upon this or similar information independently, and we would have no right to prevent them from using that ~~technology or~~ information to compete with us. If any of these events occurs or if we otherwise lose **such** protection ~~for our trade secrets~~ , the value of ~~this~~ **our proprietary** information may be greatly reduced, and our competitive position would be harmed ~~. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized~~ . We may be subject to claims that we or our employees, agents, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets **of third parties** . We have entered and may enter in the future into non- disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, contract research organizations, third- party manufacturers, consultants, advisors, potential partners, and other third parties. In addition, we may engage employees, agents, and consultants to assist us in the development of our product candidates who were previously employed at, or have previously provided or are currently providing services to, other pharmaceutical companies, including our competitors or potential competitors. We may become subject to claims or litigation where a third party asserts that we or our employees, agents, or consultants ~~inadvertently or otherwise~~ used or disclosed trade secrets or other information proprietary to such third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a ~~substantial~~ diversion from our business, and we cannot predict whether we would prevail in any such actions. In addition, third parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity, result in the disclosure of our confidential information **in** ~~as a result of~~ discovery, and adversely impact our ability to market or otherwise commercialize our product candidates and ~~technology~~ **technologies** . Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business and prospects. Even if we are successful in defending against ~~these~~ **such** claims, such litigation could result in substantial costs and be a distraction to our management team and other employees. **58** ~~We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees. 72~~ We may need to license intellectual property from third parties, and such licenses may not be available ~~or may not be available~~ on commercially reasonable terms **or at all** . ~~A third~~ **Third** ~~party~~ **parties** may hold intellectual property, including patent rights, that are important or necessary to the development or commercialization of our product candidates. in which case we would be required to obtain a license from ~~these~~ **such** third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms. Our

business would be harmed if we are not able to obtain such a license on commercially reasonable terms or at all or if a non-exclusive license is offered and our competitors gain access to the same ~~technology~~ **intellectual property rights** . In addition, even if we are able to obtain such a license, we may not have control over, nor the ability to provide input with respect to, the prosecution, maintenance, or enforcement of the patents that we license, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend ~~,~~ and enforce the licensed patents. Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts. Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development, and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale, or import our **current or future** product candidates ~~and products that may be approved in the future~~ , ~~or~~ **which could** impair our competitive position. There is a substantial amount of litigation **and administrative proceedings** , both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, inter partes review proceedings, and post- grant review proceedings ~~before the USPTO and corresponding foreign patent offices~~ . Numerous third- party U. S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third party patents or patent applications with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our product candidates. As the ~~biopharmaceutical~~ --- **pharmaceutical** industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential ~~for a certain period of time~~ , until the relevant application is published, we may be unaware of third- party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. There is also no assurance that ~~there is not~~ prior art **that** ~~of which we are aware, but which~~ we do not believe is relevant to our business ~~, which~~ may ~~, nonetheless~~ , ultimately **,** be found to limit our ability to make, use, sell, offer for sale, or import our **current or future** products **and** ~~that may be approved in the future, or~~ impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could: • result in costly litigation that may cause negative publicity or, if we were found to be infringing willfully, result in treble damages; • require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non- exclusive, which could result in our competitors gaining access to the same technology; ~~73~~ • require us to develop non- infringing technology, which may not be possible on a cost- effective basis; **59** • cause development delays; • prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law; • subject us to significant liability to third parties; or • divert the time and attention of our technical personnel and management. Although no third party has asserted a claim of patent infringement against us as of the date of this report, others may hold proprietary rights that could prevent our product candidates from being marketed. For example, we are aware of issued patents that claim a method of treatment based upon a general mode of action. These claims could be alleged to cover enitociclib in certain treatment indications. While we believe that these patents are difficult to enforce and that we would have valid defenses to these claims of patent infringement, we cannot be certain that we would prevail in any dispute ~~,~~ and we cannot be certain how an adverse determination would affect our business. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the ~~substantial~~ **large** amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business **and prospects** . We may in the future pursue invalidity proceedings with respect to third- party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings could distract our technical and management personnel from their normal responsibilities and may cause us to incur significant expenses, which could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. In addition, we may not have sufficient financial or other resources to conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent proceedings could compromise our ability to compete in the marketplace. There could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. If we do not prevail in the patent proceedings, such third parties may assert a claim of patent infringement directed at our ~~technology~~ **technologies** or product candidates, which could have a material adverse effect on our business and prospects. We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in- licenses. Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in- license, or use ~~these~~ third- party

proprietary rights. We may be unable to acquire or in- license any compositions **of matter** , methods of use, processes, or other third **-** party intellectual property rights ~~from third parties~~ that we identify as necessary for our product candidates. The licensing and acquisition of third- party intellectual property rights is ~~a~~ competitive ~~area~~ , and more established companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization ~~progress and~~ capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain ~~74~~ rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business **and prospects** . **60** Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license; • we or our licensors or collaborators might not have been the first to ~~make the inventions covered by the issued patents or patent application that we own or license; • we or our licensors or collaborators might not have been the first to~~ file patent applications covering certain of our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that the pending patent applications we own or license will not lead to issued patents; • issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • the patents of others may have an adverse effect on our business; and • we may choose not to file a patent ~~in order~~ to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property. Should any of these events occur, it could significantly harm our business **and prospects** . ~~in the future determine that there are material weaknesses in our internal control over financial reporting.Any material weaknesses or other inability to maintain effective internal control over financial reporting could adversely impact our ability to report our financial position and results of operations on a timely and accurate basis.If our consolidated financial statements are not accurate,~~ investors may not have a complete understanding of our operations and may lose confidence in our financial reporting and our business,reputation,results of operations,liquidity,financial condition,stock price ~~,~~ and ability to access the capital markets could be adversely affected.In addition,we may be unable to maintain or regain compliance with applicable securities laws,stock market listing requirements ~~,~~ and covenants regarding the timely filing of periodic reports,we may be subject to regulatory investigations and penalties,and we may face claims invoking the federal and state securities laws.Any such litigation or dispute,whether successful or not,could have a material adverse effect on our business **.80 ITEM 1B.Unresolved Staff Comments.None.ITEM 2.Properties.Our principal executive offices are located in Palo Alto,California,** and ~~prospects~~ **our lease agreement for such space expires in December 2025.Vincerx Pharma GmbH,our wholly owned German subsidiary,leases space in Monheim am Rhein,Germany.We do not own any real** General Risk Factors Our stock price has been volatile and our stock has been thinly traded, and you may not be able to sell shares of our common stock at or above the price you paid. The trading price of our common stock has been volatile and is subject to wide fluctuations. Since **the** completion of the Business Combination, our common stock has been ~~relatively~~ thinly traded. As a result of the low trading volume of our common stock, the trading of relatively small quantities of shares by our stockholders could disproportionately influence the market price of our common stock in either direction. The price for our shares could, for example, decline significantly in the event that a large number of shares of our common stock are sold on the market without commensurate demand, as compared to an issuer with a higher trading volume that could better absorb those sales without an adverse impact on its stock price. There are numerous factors that can influence our stock price volatility and trading volume, some of which are beyond our control. These factors could include: • our ability to develop or commercialize products; ~~75~~ • results of our clinical trials and nonclinical studies; • our capital **levels, capital** requirements and capital raising activities, **including** ~~such as~~ issuances of securities or the incurrence of debt; • our ability to enter into **and maintain** collaboration ~~agreements~~ **arrangements** ; • actual or anticipated fluctuations in our financial results or the financial results of companies perceived to be similar; • changes in the market' s expectations about our operating results; • success of competitors; • our operating results failing to meet the expectation of securities analysts or investors in a particular period; • changes in financial estimates and recommendations by securities analysts concerning us or the oncology industry in general; • operating and share price performance of other companies that investors deem comparable to us; • changes in laws and regulations affecting our business; • our ability to meet compliance requirements and obtain regulatory approvals; • our ability to obtain and maintain proprietary protection for our current and future product candidates; • commencement of, or involvement in, litigation involving us; • the volume of shares of our common stock available for public sale; • any major change in our board of directors or management; • sales of shares of common stock by our directors, executive officers, or significant stockholders, or the perception that such sales could occur; and • general economic and political conditions such as recessions, interest rates, inflation, fuel prices, international currency fluctuations and acts of war or terrorism. In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, particularly those in the **64** biotechnology industry. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory, and market conditions, may negatively affect the market price of our common stock, regardless

of our actual operating performance. Volatility in our stock price could subject us to securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because ~~pharmaceutical~~ **biotechnology** companies have experienced significant stock price **declines and** volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business ~~. There could be potential conflicts of interest between us~~ and **prospects** ~~certain of our stockholders, which includes some of our executive officers, due to their right to designate a majority of the members of our board of directors. Pursuant to the Voting and Support Agreement, entered into among the Legacy Holders and certain other stockholders in connection with the Business Combination (the " Voting Agreement "), the Legacy Holders, 76 including Dr. Ahmed M. Hamdy, our Chief Executive Officer, and Dr. Raquel E. Izumi, our President and Chief Operations Officer, have the right to designate seven of the nine members to our board of directors, and the stockholders who are parties to the Voting Agreement, who beneficially own approximately 33. 6 % of our outstanding common stock as of March 28, 2023, have agreed to vote for such designees. As a result, the Legacy Holders have the ability to exercise significant influence over the election of our board of directors, which in turn may create issues if and to the extent our interests and those of these stockholders diverge. We have not established at this time any procedural mechanisms to address actual or perceived conflicts of interest of such directors and officers and expect that our board of directors, in the exercise of its fiduciary duties, will determine how to address any actual or perceived conflicts of interest on a case- by- case basis. There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq. If we fail to meet the continued listing requirements and Nasdaq delists our common stock, we could face significant material adverse consequences, including: • a limited availability of market quotations for our common stock; • a determination that our common stock is a " penny stock " which will require brokers trading in our common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of our common stock; • a limited amount of news and analyst coverage; and • a decreased ability to issue additional securities or obtain additional financing in the future. Any of the foregoing could harm investor confidence and the market price of our common stock~~ . If securities or industry analysts do not publish research or reports about us, or publish negative reports, our stock price and trading volume could decline. The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us. We do not have any control over these analysts. If our operating results fail to meet analyst estimates or one or more of the analysts who cover us downgrade our common stock or change their opinion, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline. Future sales of shares of our common stock may depress the market price of our common stock. Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of ~~March 28~~ **December 31** , 2023, private warrants to purchase 3, 295, 000 shares of common stock were outstanding. Additionally, up to 6, 000, 000 Earnout Shares may be issued in connection with the Merger Agreement, provided that certain conditions are met. To the extent such private warrants are exercised **or otherwise converted into shares of our common stock** or conditions to receive Earnout Shares are met, additional shares of our common stock will be issued, which will result in dilution to the holders of our common stock and increase the number of shares eligible for resale in the public market. Such shares are eligible for sale in the public market, subject to volume limitations under Rule 144 under the Securities Act with respect to shares held by directors, executive officers, and other affiliates, and certain of such shares are eligible for sale in the public market under our currently effective Registration Statement on Form S- 3. ~~In addition, in September 2021, we sold 3, 500, 000 shares of our common stock to certain investors in a private placement, and such shares are available for resale under our Registration Statement on Form S- 3.~~ Sales, or potential sales, of substantial numbers of shares in the public market could increase the volatility of **, or adversely affect,** the market price of our common stock ~~or adversely affect the market price of our common stock~~ . 77 As a public company, we..... stock may be more volatile. 78 Our Certificate of Incorporation provides, subject to limited exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees, or stockholders. Our Certificate of Incorporation requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against directors, officers, and employees for breach of fiduciary duty, and other similar actions may be brought solely and exclusively in the Court of Chancery in the State of Delaware or, if that court lacks subject matter jurisdiction, another federal or state court situated in the State of Delaware. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our Certificate of Incorporation. In addition, our Certificate of Incorporation and **our** Bylaws provide that the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act and **65** the Exchange Act. In March 2020, the Delaware Supreme Court ~~issued a decision in Salzburg et al. v. Sciabacucchi, which~~ found that an exclusive forum provision providing for claims under the Securities Act to be brought in federal court is facially valid under Delaware law. We intend to enforce this provision, but we do not know whether courts in other jurisdictions will agree with this decision or enforce it. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees, or stockholders, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business **and prospects** . Concentration of ownership among our existing executive officers, directors, and their affiliates may prevent stockholders from influencing significant corporate decisions. As of ~~March 28~~ **December 31** , 2023, Dr. Ahmed M. Hamdy, our Chief Executive

Officer, and Dr. Raquel E. Izumi, our President and Chief Operations Officer, **together** beneficially owned, directly or indirectly, approximately ~~16~~ **17** . 7 % of our outstanding common stock, and our directors and executive officers as a group beneficially owned approximately ~~21~~ **23** . 3 % of our outstanding common stock. As a result, these stockholders will be able to exercise significant influence on all matters requiring stockholder approval, including the election of directors, any amendment of our Certificate of Incorporation **,** and approval of significant corporate transactions . In addition, certain of these....., which will increase our operating costs . We have never paid dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future. We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, we may enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions **,** and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future. ~~Any~~ **ITEM 1B. Unresolved Staff Comments. None. ITEM 1C. Cybersecurity. Risk Management and Strategy We have developed and implemented a cybersecurity policy for assessing, identifying, and managing** material ~~weaknesses in~~ **risks from cybersecurity threats and have integrated this policy into** ~~or~~ **our overall risk management framework and policies. This policy applies to all of our employees, contractors, and consultants, and any** other ~~inability~~ **users who have permanent or temporary access** to **our data and systems, regardless of their location, device, or network, and all of our employees, contractors, consultants and other users are expected to read, understand, and adhere to this policy and its associated processes and procedures. Our cybersecurity policy also encompasses the risks associated with our use of third- party service providers. We conduct assessments of our third- party service providers before engagement and** maintain ~~effective internal control over financial reporting~~ **ongoing monitoring intended to ensure compliance with our cybersecurity standards. We are subject to various cybersecurity risks that** could adversely affect our **business,** ~~ability to report our results of operations and~~ financial condition ~~accurately and in a timely manner. Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP. Our management is likewise required~~ , on a quarterly basis, to evaluate..... our ability to report our financial position and results of operations ~~on a timely and accurate basis. If our consolidated financial statements are not accurate~~ , **including intellectual** investors may not have a complete understanding..... We do not own any real property ~~. We believe that~~ **theft; fraud; extortion; harm to employees, customers,** ~~our~~ **or 66** ~~office space is adequate to meet our current needs and that additional facilities will be available on commercially reasonable terms to meet our future needs. ITEM 3. Legal Proceedings. We are not currently a party to any legal proceedings, and are not aware of any pending or threatened legal proceedings against us that we believe could have a material adverse effect on our business, operating results or financial condition. We may from time to time become involved in legal proceedings arising in the ordinary course of business. ITEM 4. Mine Safety Disclosures. Not applicable. 81~~