Risk Factors Comparison 2025-03-27 to 2024-03-29 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Risks Related to Our Financial Position and Need for Additional Capital We **previously announced that we** are **exploring strategic alternatives and also implemented certain workforce reductions and other cost- control measures to streamline our operations and focus our resources, and there can be no assurance that such measures will achieve the intended objectives, or that they will not adversely affect our business. We previously announced that we are exploring strategic alternatives, including out- licensing, merger and acquisition opportunities (including reverse mergers), the sale of assets and technologies, and winding down operations. In the fourth quarter of 2024, we implemented a series of significant workforce reductions and other cost- control measures to streamline our operations and focus our resources as we pursue our business and a potential strategic transaction. There can be no assurance that these cost- control measures will not adversely affect our business or that a strategic transaction such as the Proposed Business Combination or other strategic alternative can be achieved on a timely basis or** at **all** ~~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 December 2018~~ **Regardless of whether the Proposed Business Combination is consummated** , ~~and our operations~~ **we are currently continuing** to **pursue monetizing** ~~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~~ **our assets. There can be no assurances that** ~~partner with contract manufacturing organizations to do so on our behalf, or~~ **our efforts will be** ~~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 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. **It** ~~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~~ **would be in** a **position** ~~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 **were to** succeed in receiving marketing approval for and **partnering and / or** 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. 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 **significantly** ~~delay,~~ reduce ~~, or~~ **our operations** ~~eliminate one or more of our research~~ and **expenses,** ~~drug development programs or future commercialization efforts and~~ may not be able to continue as a going concern **, and may be forced to cease operations** . 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, and our other product candidates.~~ Even if one or more of ~~the~~ **our** product candidates **were to be** ~~that we develop is~~ approved for commercial sale, we anticipate incurring significant costs associated with **partnering and / or** commercializing any approved product candidate. These expenditures ~~will~~ **would** 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~~ **would** 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 **were** to ~~perform~~ **require** clinical trials or preclinical studies in addition to those that we currently anticipate. Other ~~41~~ unanticipated costs ~~may~~ **could** also arise. In addition, if we **were to** obtain marketing approval for any of our product candidates, we **would** 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~~ **March 21** , ~~2023~~ **2025** , we had approximately $ ~~12~~ **4** . ~~8~~ **7** million in cash ~~and cash equivalents~~ . We intend to use

our existing capital resources to **continue** ~~advance and expand our preclinical and clinical programs,~~ to fund **our operations, including** ~~certain of the milestone payments under the Bayer License Agreement and~~ our public company ~~compliance~~ costs **and expenses associated with completing the Proposed Business Combination or other alternative** , **to seek to monetize our assets** and for **36** working capital and other general corporate purposes. Based on our current business plans and assumptions, we believe that our existing cash ~~and cash equivalents~~ will be sufficient to fund our ~~operating~~ expenses and capital expenditure requirements into ~~July~~ **the third quarter of** ~~2024~~ **2025** . 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 **need** ~~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 inflation and other economic and market conditions, the 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 **significantly** ~~delay,~~ reduce ~~the scope of, suspend, or~~ **our operations and expenses** ~~eliminate one or more of our preclinical programs, clinical trials, or future commercialization efforts~~ , or curtail **or cease** our operations. 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~~ **would** be triggered prior to ~~the~~ **any** commercialization of ~~any of~~ our ~~other~~ product candidates, and we may not be able to raise additional capital 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 milestone events, some of which ~~may~~ **could** occur prior to **any** 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~~ **would** 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 pay these 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. **37** 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 **partnering and / or** 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 **commercial alliances and / or** 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. Even if we achieve profitability, we may not be able to sustain profitability in subsequent periods.~~ 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 **partner or** 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, 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 **or our** product ~~candidate~~ **candidates** ~~we may develop~~ will progress through all required testing and obtain the **necessary** 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 has transformed the dose- finding and dose optimization paradigm across oncology to emphasize selection of a dose or doses that maximizes not only efficacy of a drug but its safety and tolerability as well, which could increase the development time and costs of our clinical trials. In addition, the European Union has transitioned to full implementation of the EU Clinical Trials Regulation in January 2022, and the United Kingdom' s Medicines and Healthcare products Regulatory Agency transitioned the United Kingdom to a fully independent clinical trial regulatory framework, 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~~ such product candidate **may be marketed** 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 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. **38** 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 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. 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 such product candidates are used in combination with other therapies, they 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 such clinical trials, patients may drop out of ~~our~~ **such** 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 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 such product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of **any of** our product candidates in one jurisdiction does not guarantee that we ~~will~~ **would** be able to obtain or maintain regulatory approval in any other jurisdiction. A failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the 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 **business would be harmed. Even if** ~~ability to realize the full market potential of~~ our product candidates **were to** ~~would be harmed. 45 Even if our product candidates~~ receive regulatory approval, they ~~will~~ **would** be subject to significant post- marketing regulatory requirements and oversight. Any regulatory approvals we ~~may~~ **might** receive for our product candidates ~~will~~ **would** require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of those product candidates, may contain significant limitations related to use restrictions, warnings, precautions, or contraindications, and may include burdensome post- approval 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 **39** 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 **any of** our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, and recordkeeping for our product candidates ~~will~~ **would** be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information, reports, and registration, as well as on- going compliance with cGMP requirements and good clinical practices for any ~~clinical trials that we conduct~~ post- approval **clinical trials** . 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~~ **could** subject ~~our~~ **the** ~~company~~ **Company** to administrative or judicially imposed sanctions, **which** ~~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 processes; • warning or untitled letters; • civil and criminal penalties; • injunctions; • suspension or withdrawal of regulatory approvals; • seizures, detentions, or import bans; • voluntary or mandatory recalls and publicity requirements; • total or partial suspension of production; and • imposition of restrictions on operations, including costly new manufacturing requirements. 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, generate negative publicity, and~~ harm our business ~~and prospects~~ . There can be no assurance that we will be able to pursue accelerated or other expedited approval of any of our product candidates, and the failure to obtain such accelerated or other expedited approval would result in a longer time period to commercialization of such product candidates, which could increase the cost of development and harm our competitive position in the marketplace. ~~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 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 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. There can be no assurance that we will **have the opportunity, or** decide **,** to pursue ~~, or subsequent to FDA feedback continue to pursue,~~ accelerated approval or any other form of expedited development, review, or approval. Furthermore, even if we ~~decide~~ **were** to submit an application for accelerated approval or receive an expedited regulatory designation (e. g., breakthrough therapy designation) for **any of** our product candidates, there

can be no assurance that such submission or application would be accepted or that any expedited development, review, or approval 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. 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 guarantee that we 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 **40** 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. 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~~ **product candidates** 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 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 ~~and prospects~~. 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 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, that would violate the laws or regulations of the jurisdictions in which we operate, including healthcare, employment, foreign corrupt practices, environmental, competition, and privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and civil penalties, and could adversely impact our business ~~and prospects~~. For example, we are subject to the Foreign Corrupt Practices Act and similar anti- bribery or anti- corruption laws, regulations, 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, 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 such laws and regulations could result in, among other things, administrative, civil and criminal fines and sanctions against us, our directors, officers, or employees, the closing 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 ~~and prospects~~. **41** Risks Related to Our Dependence on Third Parties Our manufacturing processes are complex, and we do not ~~currently~~ have our own manufacturing 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 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 manufacturers. 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~~ **ever**, 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 **would** ~~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 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 improvements. 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 the development, clinical trials, regulatory approval, or commercialization of our product candidates, which~~ would harm our business ~~and prospects~~. If we fail to enter into and maintain successful collaborative arrangements or strategic alliances for our product candidates, ~~we may have to reduce or~~ **our** ~~delay our~~ **ability to develop and commercialize such** product ~~candidate~~ **candidates will be adversely affected** ~~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 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~~ **our ability to** ~~scope of, or delay, one or more of our research or development~~ ---- **develop** ~~programs~~ **and commercialize such product 42 candidates will be adversely affected**. 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, require us to relinquish important rights, limit our 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 risks that: • we may not be able to control the amount and timing of resources that our collaborators may devote to 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 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~~ **, which** could ~~delay completion of preclinical studies or clinical trials, require the conduct of bridging clinical trials, or repetition of one or more clinical trials,~~ increase ~~clinical trial costs, delay approval of product candidates, or~~ **our expenses** ~~jeopardize our ability to commence sales~~ and ~~generate revenue~~ **harm our business**. 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 **and rely** ~~. Our present development involving these product candidates relies~~ to a certain extent upon previous development conducted by Bayer or other third parties over whom we had no control and before we in- licensed 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 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 conduct clinical trials, which could delay, limit, or prevent regulatory approval for our product candidates. Due to our **reliance** ~~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 **43** their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our ~~preclinical development activities or~~ clinical trials ~~may~~ **could** be extended, delayed, suspended, or terminated, and we may not be able to obtain regulatory approval for or successfully **partner and / or** commercialize our product candidates. 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, and~~ our ~~other~~ **current** 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~~ **business** depends on our ability to protect our intellectual property and our proprietary technologies. Our **business** ~~commercial success~~ depends in part on our ability to obtain and maintain intellectual property for ~~VIP236, VIP943, VIP924, enitociclib, 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, 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. **44** 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 and prospects. Although we have licensed issued patents that cover certain of our product candidates and technologies, we do not have issued patents covering all our product candidates and technologies, and we may need additional issued patents covering such product candidates and technologies. We cannot be certain that the claims in any of our U. S. pending patent applications, corresponding international patent applications, 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. **45** In addition, although we enter 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 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. 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. 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 patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period after filing, we may not be certain that we or our licensors are the first to file any patent application related to our drug product candidates or technologies, potentially having a material adverse effect on our business and prospects. This will require us to be to be aware of the possibility of adverse determinations in any such submissions or proceedings, potentially reducing the scope or enforceability of, or invalidate, our patent rights, which would adversely affect our competitive position. 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 **46** 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. ~~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~~ **our** ~~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. 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 current or future product candidates, 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 current or future product candidates, 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 **47** patents that could prevent us from marketing our own patented products and practicing our own patented technologies. 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 or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party 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 clinical trials 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. 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. **48** 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 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. 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 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 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 Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and FDA regulatory review. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during FDA regulatory review. 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 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 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 **49** rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, 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 **to** 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 countries do not favor patent enforcement and other intellectual property protection, which could make it difficult for us to stop 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 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. **50** 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 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 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 proprietary information, our business and competitive position would be harmed. We rely on the protection of our proprietary information, including our technologies and know- how, to maintain our competitive position. Although we have taken steps to protect such information, including entering confidentiality agreements with third parties and confidential information and inventions agreements with employees, consultants, and advisors, we cannot provide any assurances that these parties would not breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies in the event of such breaches. Enforcing claims that a party illegally used or disclosed such information is difficult, expensive, and time- consuming, and the outcome is unpredictable. Moreover, third parties may obtain or come upon this or similar information independently, and we would have no right to prevent them from using that information to compete with us. If any of these events occurs or if we otherwise lose such protection, the value of our proprietary information may be greatly reduced, and our competitive position would be harmed. 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 **51** 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 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 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 discovery, and adversely impact our ability to market or otherwise commercialize our product candidates and 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 such claims, such litigation could result in substantial costs and be a distraction to our management team and other employees. ~~58~~ We may need to license intellectual property from third parties, and such licenses may not be available on commercially reasonable terms or at all. Third 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 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 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 **business** ~~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, 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. 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 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, 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, **52** 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 prior art that we do not believe is relevant to our business may, ultimately, be found to limit our ability to make, use, sell, offer for sale, or import our current or future products and 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; • require us to develop non- infringing technology, which may not be possible on a cost-effective basis **or at all** ; ~~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 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 **capital** ~~additional funds~~ or otherwise have a material adverse effect on our business ~~and prospects~~ . **If we were to** ~~We may in the future~~ pursue invalidity proceedings with respect to third- party patents ~~. The~~ **, the** outcome following legal assertions of invalidity ~~is~~ **would be** 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~~ **fail to** prevail in ~~the~~ **any such** patent proceedings, such third parties may assert a claim of patent infringement directed at our technologies or product candidates, which could have a material adverse effect on our business ~~and prospects~~ . **53** ~~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 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 that we identify as necessary for our product candidates. The licensing and acquisition of third- party intellectual property rights is competitive, 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 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 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 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 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~~ . Risks Related to Operating as a Public Company If we are not able to maintain compliance with the continued listing requirements of The Nasdaq Capital Market, our common stock may be delisted, which could negatively impact the liquidity and price of our common stock, our ability to **complete a business combination or** access the capital markets, and the confidence of investors and others. On September 14, 2023, we received written notice from The Nasdaq Stock Market LLC (" Nasdaq ") that the closing bid price of our common stock for the prior 30 consecutive business days was lower than the minimum bid price requirement of $ 1. 00 per share. On January 12, 2024, we received written notice from Nasdaq that we had regained compliance with the minimum bid price requirement. ~~However~~ **On May 22** , **2024, we received a subsequent notice from Nasdaq that based upon the closing bid price of our shares of common stock for the prior 30 consecutive business days was again lower than the minimum bid price requirement In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), we were provided with a period of 180 calendar days, to November 18, 2024, to regain compliance with the minimum bid price requirement. On November 14, 2024, we submitted a request to Nasdaq for an additional 180- day extension to May 19, 2025 to regain compliance with the minimum bid price requirement, which request was granted on November 19, 2024. On January 27, 2025, we effected a 1- for- 20 reverse stock split. On February 11, 2025, we received written notice from Nasdaq that we had regained compliance with the minimum bid price requirement. Although we have regained compliance with the Nasdaq minimum bid price requirement, as of the date of this report, our common stock is trading below $ 1. 00 per share. Because we have effected a reverse stock split within the past year, if our common stock fails to meet the minimum bid price requirement, our common stock will be delisted unless we submit a timely request for a delisting hearing, and are granted a stay of delisting until the conclusion of the hearing process.** ~~there~~ **There** can be no assurance that we will be able to continue to maintain **54** compliance with the Nasdaq continued listing requirements **or achieve a stay of delisting** , and if we fail to do so and Nasdaq delists our common stock, we could face material adverse consequences, including: • limited availability of market quotations and decreased liquidity for our common stock, resulting in a decline in the trading price of our common stock; • adverse impact on the ability of stockholders to sell our common stock; • limited news and analyst coverage and negative publicity; and • decreased ability to raise capital and potential loss of confidence by investors, suppliers, customers, collaborators, and employees. ~~61~~ As a public company, we face ~~increased~~ **significant** expenses and administrative burdens, which could have an adverse effect on our business, financial condition, and results of operations. As a public company, we face ~~increased~~ **significant** legal, accounting, administrative, and other costs and expenses. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, the Public Company Accounting Oversight Board, the securities exchanges, and the rules and regulations thereunder impose additional reporting and other obligations on public companies. Compliance with public company requirements results in ~~increased~~ **significant** costs and makes certain activities more time- consuming, including expenses associated with SEC reporting requirements. In addition, if any issues in complying with those requirements are identified (for example, if the auditors identify a material weakness or significant deficiency in our internal control over financial reporting), we could incur additional costs in rectifying those issues, and the existence of those issues could adversely affect our reputation or investor perceptions of us and also increase our costs of obtaining director and officer liability insurance. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on our board of directors or as executive officers. The ~~additional~~ reporting and other obligations imposed by these rules and regulations increase our legal and financial compliance costs and the costs of related legal, accounting, and administrative activities. These ~~increased~~ costs require us to divert a significant amount of money that could otherwise be used to expand our business and achieve our strategic objectives. Advocacy efforts by stockholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs. We are an " emerging growth company " within the meaning of the Securities Act, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our stock less attractive to investors. We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not " emerging growth companies, " including exemption from compliance with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, and stockholder approval of any golden parachute payments not previously approved. We will cease to be an emerging growth company on the date that is the earliest of (a) the last day of the fiscal year in which we have total annual gross revenue of $ 1. 235 billion or more, (b) December 31, 2025, the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering, (c) the date on which we have issued more than $ 1. 0 billion in nonconvertible debt during the previous three years, or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Even after we no longer qualify as an emerging growth company, we may still qualify as a " smaller reporting **55** company, " which would allow us to take advantage of many of the same exemptions from disclosure

requirements, including exemption from compliance with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in this report and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and the market price of our common stock may be more volatile. ~~62~~ Our failure to timely and effectively implement controls and procedures required by Section 404 (a) of the Sarbanes- Oxley Act could have a material adverse effect on our business. As a public company, we will be required to provide management' s attestation on internal controls in the future under Section 404 (a) of the Sarbanes- Oxley Act. Management may not be able to effectively and timely implement controls and procedures that adequately respond to these increased regulatory compliance and reporting requirements. If we are not able to implement the additional requirements of Section 404 (a) in a timely manner or with adequate compliance, we may not be able to assess whether our internal controls over financial reporting are effective, which may subject us to adverse regulatory consequences and could harm investor confidence and the market price of our common stock ~~. Our management has limited experience in operating a public company. Our executive officers have limited experience in the management of a publicly traded company and may not be able to effectively manage a public company that is subject to significant regulatory oversight and reporting obligations under federal securities laws. Their limited experience in dealing with the increasingly complex laws pertaining to public companies could be a significant disadvantage in that it is likely that an increasing amount of their time may be devoted to these activities, which will result in less time being devoted to our management and growth. We may not have adequate personnel with the appropriate level of knowledge, experience, and training in the accounting policies, practices, or internal controls over financial reporting required of public companies in the United States. The development and implementation of the standards and controls necessary for us to achieve the level of accounting standards required of a public company in the United States may require costs greater than expected. It is possible that we will be required to expand our employee base and hire additional employees to support our operations as a public company, which will increase our operating costs~~ . Any material weaknesses in or other inability to maintain effective internal control over financial reporting could adversely affect our 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 the effectiveness of our internal controls and to disclose any changes and material weaknesses identified through such evaluation in those internal controls. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. We have in the past and may 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 and prospects. ~~63~~ 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 **LSAC** Business Combination, our common stock has been 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 **56** 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; • results of our clinical trials and nonclinical studies; • our capital levels, capital requirements and capital raising activities, including issuances of securities or the incurrence of debt; • our ability to enter into and maintain collaboration 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 biotechnology companies have **57** 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 and prospects. 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 December 31, ~~2023~~ **2024** , ~~private~~ **we had outstanding** warrants to purchase ~~3~~ **an aggregate of approximately 1** , ~~295~~ **810** , 000 shares of common stock ~~were outstanding~~ **(adjusted to give effect to the 1- for- 20 reverse stock split)** . Additionally, up to **200** ~~6, 000~~ , 000 Earnout Shares **(adjusted to give effect to the 1- for- 20 reverse stock split)** may be issued in connection with the ~~Merger Agreement~~ **LSAC Business Combination** , provided that certain conditions are met. To the extent ~~such private~~ **that any of the** 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~~ -- **sale** 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~~ . 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. 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 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. **58** ~~Concentration of ownership among our existing executive officers, directors, and their affiliates may prevent stockholders from influencing significant corporate decisions. As of 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 17. 7 % of our outstanding common stock, and our directors and executive officers as a group beneficially owned approximately 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.~~ 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. ITEM 1B. Unresolved Staff Comments. None. **59** ~~ITEM 1C. Cybersecurity. Risk Management and Strategy We have developed and implemented a cybersecurity policy for assessing, identifying, and managing material risks from cybersecurity threats and have integrated this policy into our overall risk management framework and policies. This policy applies to all of our employees, contractors, and consultants, and any other 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 ongoing monitoring intended to ensure compliance with our cybersecurity standards. We are subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees, customers, or 66~~